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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91215699
Party	Defendant Holaira, Inc.
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Date	11/16/2015
Attachments	Non-Confidential Transcript (FULL) of Trial Testimony of Dr. Dennis Wahr.pdf(222505 bytes) Executed Errata Sheet of Transcript of Trial Testimony of Dr. Dennis Wahr.pdf(71683 bytes) Non-Confidential Transcript (CONDENSED) of Trial Testimony of Dr. Dennis Wahr.pdf(171914 bytes) Exhibit 3 (Non-Confidential) to Dr. Wahr Transcript.pdf(289725 bytes) Exhibit 4 (Non-Confidential) to Dr. Wahr Transcript.pdf(73738 bytes) Exhibit 5 (Non-Confidential) to Dr. Wahr Transcript.pdf(825234 bytes) Exhibit 6 (Non-Confidential) to Dr. Wahr Transcript.pdf(61712 bytes) Exhibit 7 (Non-Confidential) to Dr. Wahr Transcript.pdf(607094 bytes) Exhibit 8 (Non-Confidential) to Dr. Wahr Transcript.pdf(2785543 bytes) Affidavits of Service 7-28-15 and 11-16-15.pdf(91074 bytes)

1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD
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4 Boston Scientific Corporation and
5 Asthmatx, Inc.,
6 Opposers, Opposition No. 91215699
7 and
8 Holaira, Inc.,
9 Applicant.

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15 DEPOSITION OF
16 DR. DENNIS WAHR

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24 Taken July 2nd th, 2015 By Alexis Jensen

25

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19 PREVIOUSLY-MARKED EXHIBITS REFERRED TO:
20 (NONE)

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1 THE DEPOSITION OF DR. DENNIS WAHR,
2 is taken on this 2nd day of July, 2015, at
3 Oppenheimer, Wolff & Donnelly, LLP,
4 Campbell Mithun Tower, Suite 2000,
5 Minneapolis, Minnesota, commencing at
6 9:07 a.m.

7 DR. DENNIS WAHR,
8 having been called as a witness, being duly
9 sworn, testified as follows:

10 EXAMINATION

11 BY MR. HANSEN:

12 Q. Good morning, Dr. Wahr. I'd like to start
13 out today by just having a little bit of a
14 discussion about your background, okay?

15 A. Okay.

16 Q. Let's start with your education, starting
17 with college, and if you would, take me
18 through to your highest professional degree
19 or certification.

20 A. Okay. I went -- I went undergrad college to
21 a small liberal arts school in Michigan
22 called Albion College, A-L-B-I-O-N. Then I
23 went to medical school at Wayne State
24 University in Detroit, and then did my
25 internal medicine residency, three years, at

1 the University of Michigan. Then I did my
2 cardiology fellowship at the University of
3 California, San Francisco, went to UCSF,
4 three years there, where I became an
5 interventional cardiologist.

6 I spent one year on faculty there
7 at UCSF. Then I went back to Michigan,
8 where I practiced cardiology for about
9 12 years at -- you know, in Ann Arbor, where
10 I was in private practice at St. Joseph
11 Mercy Hospital and was a clinical professor
12 of cardiology at the University of Michigan.

13 Then I took a leave of absence for
14 one year to come to Minneapolis and -- and
15 become a medical device entrepreneur. I
16 started my own medical device company, and
17 that was in the year 2001, and since -- and
18 never went back. I never went back and
19 practiced -- I took a one-year sabbatical
20 and never went back.

21 Q. When?

22 A. And have been here ever since, for the last
23 15 years.

24 Q. Were you a Board-certified interventional
25 cardiologist?

1 A. Yes, yes, I was what they called triple
2 Board-certified. You know, I was
3 Board-certified in internal medicine. I was
4 Board-certified in cardiology and
5 Board-certified in interventional
6 cardiology; all three different levels of
7 Board certification.

8 Q. Okay. What's the -- what's the difference
9 between cardiology and interventional
10 cardiology?

11 A. Cardiologists do -- there's probably four
12 big divisions of cardiology. There's
13 interventional cardiology; there's
14 electrophysiology; there's diagnostic
15 cardiology, which would be things like
16 echocardiographies and MRI scans, you know,
17 they're almost like radiologists; and then
18 there's intensive care cardiology, you know,
19 working in ICUs and things like that.

20 And they all have their separate
21 Boards, so, you know, it just keeps getting
22 more and more subspecialized. So, a
23 cardiologist is kind of a generalist of
24 cardiology, and, you know, now there's these
25 four subspecialties of cardiology.

1 Q. Okay.

2 A. It's pretty amazing. It's pretty
3 ridiculous.

4 Q. What -- what does an interventional
5 cardiologist do? Can you just describe
6 that?

7 A. Yeah, interventional cardiology is the part
8 of cardiology that does procedures on
9 patients, you know, and that's really the
10 first thing they started doing were
11 angioplasties. You know, in the mid '80s,
12 that really was origin of interventional
13 cardiology, fixing blocked arteries, working
14 through a pinhole.

15 That was the beginning of
16 interventional cardiology, the field of
17 interventional cardiology, but now it's
18 gradually expanded to where interventional
19 cardiologists do many different types of
20 procedures, all minimally -- from a
21 minimally-invasive approach. That's really
22 what defines it.

23 Q. When you were practicing as an
24 interventional cardiologist, did you use
25 medical devices?

1 A. Absolutely, yeah.

2 Q. What -- what sorts of medical devices?

3 A. Well, certainly balloon angioplasty
4 catheters; stents, you know, the wire mesh
5 cylinders that we put in to scaffold open
6 blood vessels; atherectomy devices, which is
7 where you go in and carve out the plaque,
8 you know, and remove it; closure devices,
9 you know, where you go through pinholes to
10 close defects in the heart, you know, holes
11 between to atria and the ventricles, and
12 congenital abnormalities that are repaired
13 now through pinholes.

14 All of these things replaced the
15 need to have to have open-chest surgery.
16 And now, of course, the -- another big one
17 are the -- literally the percutaneous
18 valves. I mean, literally replacing valves
19 just through pinholes. I mean, those would
20 be the major areas of interventional
21 cardiology.

22 Q. Turning now to the entrepreneurial aspect of
23 your background.

24 In 2001, you mentioned that you
25 started --

1 A. Yes.

2 Q. -- a medical device company.

3 What medical device company was
4 that?

5 A. It was called Velocimed, V-E-L-O-C-I-M-E-D.

6 Q. What types of product or products did --

7 A. We made --

8 Q. -- Velocimed make?

9 A. We made three different medical products.

10 One was what's called an -- and at the time
11 this was really the first one. It's
12 something called an embolic protection
13 device.

14 One of the risks of doing
15 angioplasty was sometimes you could go in,
16 inflate a balloon to dilate an artery, but
17 debris could break off and go downstream,
18 you know, and if that happened, you could
19 have damage downstream. Like if that would
20 break off and go to an important place, like
21 the brain or the kidney or something like
22 that, that was one of the areas of
23 complications.

24 So, we created a little basket that
25 could catch that that we'd put in first and

1 then did the angioplasty, and if anything
2 went down, you would catch it.

3 Second product was something called
4 a PFO closure device, which was an
5 umbrella -- a little umbrella, miniature
6 umbrella, that you could put through a
7 pinhole and go in and close a hole between
8 the right and left atrium of the heart.

9 And the third one was what we
10 called a navigation catheter, because one of
11 the things that would start cardiologists
12 from being able to do a procedure is if they
13 couldn't get to that spot, you know, through
14 the curving blood vessels. So, we made a
15 catheter that could be, using a joystick,
16 directed to go around sharp curves.

17 St. Jude bought all three of those
18 products in the year -- I started the
19 company in 2001. St. Jude bought that
20 company in 2005, and all three products are
21 still -- are still being sold around the
22 world today. That was the first company.

23 Q. Were those products approved for sale by the
24 FDA?

25 A. All of them eventually achieved worldwide

1 approval, including US.

2 Q. And what -- are you aware that the FDA
3 classifies medical devices in one of three
4 separate classes?

5 A. Yes.

6 Q. And what -- what class of device were the
7 three devices sold by or created by
8 Velocimed?

9 A. Well, the embolic protection device and the
10 PFO closure device were Class 3 devices.
11 The three classes are, you know, literally
12 1, 2, 3, where 3 is the -- the highest level
13 of sophistication, and, therefore -- you
14 know, or potential risk and the most novel,
15 which then means it needs the most testing.

16 Class 1 devices are typically
17 devices that are the least amount of risk,
18 and they're often -- they are often devices
19 that are copies of other devices that are
20 out there, that have predicates, and
21 everything's known about them, and it's just
22 kind of like one more copy doing the copycat
23 thing. You know, they can get a label as a
24 Class 1. Label 2 is somewhere in between.

25 The navigation device was Class 2.

1 Q. Got it.

2 A. But then my second company Lutonix,
3 L-U-T-O-N-I-X, that was a Class 3 device
4 too.

5 Q. When did -- did you found Lutonix?

6 A. I founded both of these companies.

7 Q. And when -- when did Lutonix come into
8 being?

9 A. 2007, and CR Bard bought that company in
10 2000 -- in December of 2011.

11 Q. What product did Lutonix create?

12 A. We made an angioplasty balloon that had a
13 drug coating on it, and so, when you did
14 the -- so, when you would do the
15 angioplasty, the drug would transfer to the
16 blood vessel wall, and the drug would then
17 prevent the artery from re-narrowing, you
18 know, after you did the angioplasty.

19 Q. Is that angioplasty balloon approved by the
20 FDA?

21 A. Yes.

22 Q. And you mentioned that it was a Class 3
23 device?

24 A. 3, yep. First -- first drug-coated
25 angioplasty balloon in the world to be

1 approved by the FDA. We got approval in
2 2012.

3 Q. Where are you currently employed Dr. Wahr?

4 A. Holaira, H-O-L-A-I-R-A.

5 Q. And when did you join that company?

6 A. I joined it in September of 2012.

7 Q. Did you found that company as well?

8 A. No.

9 Q. Who founded Holaira?

10 A. An individual called Marty Mayse, and
11 co-founded along with another person, an
12 engineer named Steve Dimmer. They were
13 co-founders.

14 Q. When you joined the company in 2012, was it
15 called Holaira?

16 A. No, the company was originally founded in
17 2008. That's when Marty Mayse and Steve
18 Dimmer founded the company. So, when I
19 joined the company, it was already four
20 years old, and the original name of the
21 company was InterventionalPulmonarySolutions
22 [sic], all one word. They -- they called it
23 IPS for short, to abbreviate it.

24 Q. Let's talk about the Holaira -- well,
25 actually, I should first ask you: What's

1 your role at Holaira? What do you do there?

2 A. I'm the CEO.

3 Q. And have you always been the CEO?

4 A. Yeah -- well, since they hired me, yeah, for
5 the last three years, yeah.

6 Q. Okay. Let's talk about the -- the products
7 that Holaira creates.

8 What -- what is the product that
9 Holaira creates?

10 A. We -- we have a product that's called -- the
11 name of the product is dNerva, and what it
12 is is it's a -- we use it to do a procedure
13 called targeted lung denervation, and the --
14 and the system that does it we call the
15 Holaira Lung Denervation System.

16 Q. Can you describe for me what components
17 there are to the Holaira Lung Denervation
18 System?

19 A. Yes, there are -- there's a -- the system
20 has a console. The console does really
21 three -- three things that are important.
22 It has a -- it's the generator for the
23 energy, you know, RF energy, radio frequency
24 energy, which is the power we use to -- for
25 the therapeutic effect, which I'll describe

1 in a minute.

2 It also has the pump in it, because
3 we have to circulate cold water, you know,
4 through the catheter while we do it. It
5 also has a -- so, therefore, it also has a
6 chilling -- a chiller in the console. And
7 then, of course, it has a user interface,
8 you know, which is a software program.

9 The console runs the dNerva
10 catheter, and the catheter is the active --
11 you know, is the therapeutic part of the
12 product, and the dNerva catheter is used by
13 an interventional pulmonologist. The
14 interventional pulmonologist takes the
15 dNerva catheter, and he puts it through the
16 working channel of a flexible bronchoscope,
17 you know, and flexible bronchoscopes are
18 something that interventional pulmonologists
19 have used for years.

20 It's still -- it's a flexible
21 catheter that goes down -- you know, in
22 through your mouth, down the trachea, and
23 they can look around inside the lungs with
24 this, but our catheter goes through the
25 working channel inside that bronchoscope,

1 and when -- when the interventional
2 pulmonologist puts it down, he can position
3 it in both the right mainstem bronchus first
4 and then the left mainstem bronchus. You
5 can actually do it in either sequence.

6 That could be -- the working end of
7 the catheter has an electrode on it, which
8 is used to deliver the energy, and when that
9 electrode is positioned correctly inside the
10 right or left main bronchus, the energy can
11 be turned on, so that it delivers thermal
12 energy to the wall of the -- the main
13 right -- the right and left mainstem
14 bronchus that can denature the nerves that
15 go to the lung permanently, so that those
16 nerves are interrupted.

17 And what's great about that is
18 those nerves are what -- if you -- if you
19 interrupt those nerves, it allows the
20 airways to dilate, open.

21 Q. Let's just back up for a second.

22 You -- you referred to something
23 called a bronchus?

24 A. Yes.

25 Q. What is the bronchus?

1 A. Anatomically, your main airway. It comes
2 from your vocal cords. It's called the --
3 down to -- its first branch point is the
4 trachea, and that's the big airway. You can
5 feel it, you know, right -- right in your
6 throat.

7 When that comes -- when that gets
8 down into the middle of the chest, it
9 branches into two main -- two large
10 branches, and those are call the right and
11 left mainstem bronchus, and then the
12 mainstem bronchus, in turn, branch into
13 multiple other airways, and then they keep
14 subdividing into -- and goes down into all
15 of the little billions of airways, you know,
16 out in the lungs.

17 Q. Okay. So, the -- the bronchus -- the
18 mainstem bronchus is outside of the lungs?

19 A. Yes, you're not technically in the lungs
20 yet.

21 Q. Okay. And then the bronchus stems out from
22 the mainstem bronchus and goes into the lung
23 fields?

24 A. Yeah, it goes -- it goes -- basically, you
25 have the mainstem bronchus, and then you

1 have secondary bronchi and then tertiary.

2 You know, it's just dividing and dividing

3 and dividing.

4 Q. And describe for me, again, where the --

5 where within in the body the dNerva catheter

6 is used?

7 A. In the right and left mainstem bronchus, in

8 just those first major divisions.

9 Q. Okay.

10 A. It never goes down into the lung fields.

11 Q. And the -- what -- what condition is Holaira

12 seeking approval from the FDA to treat with

13 this device?

14 A. Well, COPD, Chronic Obstructive Pulmonary

15 Disease, is the disease process, and in

16 patients that have COPD, COPD is

17 characterized by overactive nerves, you

18 know, that -- that are causing -- and these

19 overactive nerves cause the airways to be

20 constricted, you know, kind of in spasms, so

21 to speak, and up until this point in time,

22 the way COPD patients have been treated are

23 with inhalers.

24 And, of course, you see this on

25 television all the time. Spiriva is the

1 leading selling pulmonary drug in the world,
2 maybe the first or second leading selling
3 drug of any kind in the world. You know,
4 the inhaler that you see people who can't
5 breathe puff on.

6 And what that -- the way that
7 inhaler works, it goes down, and it
8 literally is trying to block the nerves, you
9 know, that go to the lungs so the airways
10 can open up. What we're trying to do, we're
11 going in, and we're -- by using this
12 RF energy and the right and left mainstem
13 bronchus, we're trying to ablate those
14 nerves, so that we -- so that we can
15 permanently -- get a permanent dilation, so
16 that you have a permanent bronchodilation.
17 So, it would become an alternative therapy
18 to drugs or even an additive, where we
19 actually know it would be an additive to
20 drugs, and there's a reason for that, to
21 benefit.

22 Q. Let's talk about the -- a little bit more
23 about the medical procedure in which the
24 Holaira Lung Denervation System is used.

25 You mentioned a name for the

1 medical procedure itself. What was that
2 again?

3 A. Targeted lung denervation.

4 Q. Okay. And where is targeted lung
5 denervation performed? Like in what kind of
6 setting?

7 A. It's in a hospital, a pulmonology procedure
8 room. It's in a special room that -- where
9 hospitals do these bronchoscopies
10 procedures.

11 Q. What -- who performs the procedure?

12 A. An interventional pulmonologist.

13 Q. What's an interventional pulmonologist?

14 A. Well, it goes -- it kind of goes back to the
15 same thing about when I talked about
16 interventional cardiologist.

17 Until recently, until literally a
18 couple years ago, the -- the highest level
19 of certification within the field of
20 pulmonary was a Board-certified
21 pulmonologist, and these were doctors that
22 did bronchoscopies, you know, just that were
23 diagnostic, you would go and look around to
24 see what was in the lungs.

25 But in the last -- over the last

1 number of few years, similar to what had
2 happened 15 or 20 years ago in cardiology, a
3 new field has arisen of interventional
4 pulmonology, where pulmonologists can do
5 additional training to become skilled at
6 actually doing invasive procedures, and this
7 group are what we refer to as the
8 interventional pulmonologists, and to be --
9 and that is a fully now recognized Board
10 certification-required subspecialty of
11 pulmonology, where they literally have to do
12 a two-year fellowship after training all the
13 previous stuff, do two additional years of
14 interventional pulmonology and then pass the
15 Boards to be a card-carrying credentialed
16 interventional pulmonologist, and they --
17 they do everything -- well, I shouldn't say
18 they do everything.

19 They do an awful lot. They do a
20 lot of different procedures now just through
21 the bronchoscope that used to require
22 open-chest surgery. You know, the same
23 story again like what happened 20 years ago
24 in cardiology, and they'll do everything
25 from putting in stents to dilating blocked

1 airways to resecting tumors to, you know,
2 removing foreign bodies, just lots of
3 things.

4 So, we as a -- our procedure,
5 targeted lung denervation, is one of an
6 array of things that they do.

7 Q. You mentioned that -- how many of -- roughly
8 how many interventional pulmonologists are
9 there in the United States, if you know?

10 A. Today, there are about 150 roughly, about
11 150. So, you can kind of think of it as
12 each state -- if all states were average
13 size, there would be two or three in a
14 state.

15 It will grow. You know, the -- the
16 fellowship programs that train them are
17 turning out about, you know, seven or eight
18 new ones a year, you know, in the US, you
19 know, the specialized places that are
20 formally training them. So, that number
21 will -- I expect will slowly grow.

22 Q. Okay. Let's discuss a little bit how the
23 company changed names from IPS to Holaira,
24 and to assist with the -- the discussion,
25 I'll mark and hand you an exhibit.

1 A. Sure.

2 (Exhibit Number 1 was marked.)

3 BY MR. HANSEN:

4 Q. Dr. Wahr, you've been handed what's been
5 marked as Wahr Exhibit 1.

6 Do you recognize this document?

7 A. Yes.

8 Q. What is it?

9 A. This is -- these are documents that we put
10 together not long after I took over as CEO
11 to help guide, you know, our renaming
12 process, you know, and also, you know, some
13 Board presentations that -- where we
14 actually conveyed some of this information
15 to our Board of Directors --

16 Q. Okay.

17 A. -- about why we were doing it.

18 Q. And was this a presentation present to the
19 Holaira Board of Directors?

20 A. Yes, this first one here, the open session
21 of the Board meeting. I mean, this was part
22 of the Board meeting where -- you know,
23 Board meetings have generally two parts.

24 They have what's called an open
25 session, where key company executives are

1 included; and then there's what's called a
2 closed, where it's just me with the Board of
3 Directors period. You know, that's the part
4 where you talk about things like
5 compensation and confidential stuff that you
6 wouldn't want to have other people sitting
7 in on.

8 Q. During the --

9 A. Open session.

10 Q. -- open session, if you'd flip to page --
11 the twelfth slide in, which is -- has the
12 Bates number on the bottom right,
13 Holaira 627?

14 A. Yep.

15 Q. There is a -- appears to be a discussion
16 about branding activities?

17 A. Yep -- yes.

18 Q. What was the purpose of this -- the
19 inclusion of this slide in the presentation?

20 A. Well, I was -- I introduced it -- as you
21 noticed on the first page, the company was
22 still called Innovative Pulmonary Solutions
23 at this time, but I wanted to -- and I --
24 this -- this was really my first Board
25 meeting, you know, because I was hired in

1 September, and this was December, and so,
2 this was my very first Board meeting that I
3 led, and I had already decided by that point
4 that I wanted to change the name of the
5 company, and this was my starting to
6 socialize that concept to the Board.

7 Now, you have to realize this was a
8 Board of Directors that had been with this
9 company for four years, you know, and so,
10 they were pretty -- you know, they were very
11 familiarized with the previous name, and so,
12 I just didn't want to come in and say I'm
13 changing, so how I'll commonly do things is
14 I'll introduce something and socialize it
15 and then -- then come back with a
16 recommendation at the next Board meeting.

17 It's a good way to run a company,
18 by the way, if you ever do this. Don't
19 blind-side your Board with just radical
20 stuff in the cold.

21 So, this was socializing the
22 concept that I was working my way towards
23 rebranding the company, which is a way of
24 saying, we're going to change the name,
25 we're going to change the Website. You

1 know, we're going to -- you know, our
2 materials that are shown publicly, you know,
3 we're going to rethink.

4 Q. Why did you want to move away from the IPS
5 name?

6 A. Well, this was my third time around the
7 track, you know, with a company, and so,
8 while I don't consider myself a marketing
9 person, I'm used to working with marketing
10 people, and I do believe what they say.

11 And, to me, there were a couple --
12 there was a few problems with Innovative
13 Pulmonary Solutions.

14 Q. What were those problems?

15 A. Well, one is -- is that marketing people
16 will tell you that they really -- they would
17 never recommend the name of a company that
18 goes much more than two or three syllables.
19 Innovative Pulmonary Solution had 11. It's
20 too many words, you know, to be efficient,
21 you know.

22 And the second thing is is that it
23 was so long that you couldn't even fit it
24 into some URL boxes. You know, when you go
25 to type in your emails and stuff, it

1 wouldn't fit, and, you know, you'd run out
2 of space, and then you were just stuck on a
3 lot of forms. I found that particularly
4 irritating.

5 The third thing was it was just
6 kind of a sentence. You know, it wasn't
7 really a unique word. Marketing people and
8 branding people want you to create your own
9 unique word. Because it wouldn't fit into
10 URL addresses, the company started calling
11 itself IPS for short, which is a
12 three-letter acronym, but the problem with
13 IPS was, one thing, marketing people don't
14 like acronyms, but, number two, it was
15 already trademark. I mean, in fact, it's
16 trademarked by about 15 people worldwide for
17 all kinds of different things. There's
18 absolutely nothing unique about IPS, you
19 know, as a three-letter thing -- thing out
20 there.

21 So -- so, for all of those reasons,
22 I felt we needed -- and since the company --
23 I had just become the new CEO, part of
24 becoming the new CEO was we were going to
25 move the company -- we decided we'd move the

1 company from Seattle, where it had been the
2 first four years, to Minneapolis.

3 So, we were moving the company, and
4 it's going to be a new entity, you know,
5 here in Minneapolis, of which the people in
6 Minneapolis didn't even know -- you know,
7 there was no memory of the old name. So, it
8 was the perfect time to change the name.

9 Q. On the -- on slide 12, the third bullet
10 point down says: Need image that
11 demonstrates we are different from
12 competition, relevant to the target
13 audiences and credible.

14 Do you see that?

15 A. Yep.

16 Q. What was meant by "demonstrates we are
17 different from competition"?

18 A. This is a Class 3 device, first time -- and
19 it's very novel, first time anything like
20 this has ever been done in humans. You want
21 a name that is not confused with anything
22 else, you know, that is totally unique, that
23 will -- a new word -- a new word, you know,
24 created that will become the image of your
25 product, you know, that no physician will

1 ever find confusing.

2 You know, that's fundamental --
3 that's what's fundamental. You don't -- you
4 know, when the Google people decided to have
5 a -- a search engine that you could find
6 anything on the Internet in 100th of a
7 second, they wanted a word that nobody had
8 seen before, and that's -- they created the
9 word "Google," which now everybody thinks
10 has been around for a century, when, in
11 fact, it's only been around for ten years,
12 because it was brand new. That's what
13 you're trying to do.

14 Q. After this Board meeting, did the -- did the
15 IPS continue in the process of rebranding?

16 A. Yes, the Board -- when I introduced this,
17 the Board gave me -- they said, yes, we're
18 interested in having this done, go do it.

19 Q. And what -- did Holaira, or IPS at the time,
20 retain any third-party entities to assist in
21 that process?

22 A. Yep, it's on here. You know, I had already
23 started the process, you know, with a
24 marketing consultant named Lorraine Wright
25 on the slide, and Lorraine, in turn, was

1 working with a marketing company called
2 Six Degrees.

3 Q. Okay.

4 A. Lorraine is not an employee of Six Degrees.
5 They are two different things. So, Lorraine
6 is our marketing person basically.

7 MR. HANSEN: Let's mark that
8 exhibit.

9 (Exhibit Number 2 was marked.)

10 BY MR. HANSEN:

11 Q. Before we get into this next exhibit,
12 Dr. Wahr, you mentioned that Lorraine Wright
13 is not an employee?

14 A. Right.

15 Q. Although she's not an employee, is she
16 treated like -- as if she's an employee with
17 respect to her job function?

18 A. Yes, she's our -- she's our only marketing
19 person we have. She does 100 percent of our
20 marketing activities, which, because we're
21 still a pre-revenue company, clinical stage,
22 as I call it, we don't really have a need
23 yet for a full-time marketing executive.

24 So -- so, that's why she's still at
25 consultant status. I would estimate she

1 probably spends about 50 percent of her time
2 working with us, but she has some other
3 clients, but she's our sole person, and she
4 carries a Holaira business card, has a
5 Holaira -- has a Holaira email address, and
6 she -- she is our -- she functions as if
7 she's a full-time employee. All
8 marketing-type questions, you know, that
9 flow through -- or inquiries from the
10 Website flow through her.

11 Q. Let's turn to Exhibit 2.

12 A. Okay.

13 Q. Have you seen Exhibit 2 before, Dr. Wahr?

14 A. Yes.

15 Q. What is Exhibit 2?

16 A. These are the materials that were put
17 together by Six Degrees working with
18 Lorraine Wright that were literally the --
19 the documents we worked off of in our
20 company meetings as we started through a
21 methodical process of -- of considering
22 various alternatives for renaming the
23 company.

24 Q. If you turn to the third slide in, which is
25 Bates number Holaira 48, there's a slide

1 entitled: Naming Considerations?

2 A. Yes.

3 Q. The first bullet point says: The new name
4 must be shorter, simpler, fewer syllables.

5 What is that in reference to?

6 A. That's in reference to our previous name of
7 Innovative Pulmonary Solutions that had 11
8 syllables.

9 Q. Okay. If you turn to Holaira 50, which is
10 another couple of slides in, it's entitled:
11 Metrics for Naming?

12 A. Yep.

13 Q. Can you describe what the purpose of this
14 slide is?

15 A. Yes, this is a -- this was a slide that
16 Six Degrees put together. I would say that
17 it's pretty much a boilerplate that
18 marketing firms use for how you -- you know,
19 it was not unique to us. It was unique to
20 what they do every time regardless of the
21 client, in terms of, when you start through,
22 how do you invent a new name or new word.

23 By the way, this is kind of -- I
24 found this -- found this fascinating when I
25 got into this. There is no word in

1 Webster's Dictionary that's not trademarked.
2 So, you can't name the company anything of a
3 word that exists. There -- whatever the
4 thousands of words, they're all trademarked.

5 So, the only way you can create a
6 new trademark is to come up with a brand new
7 word. Isn't that amazing? There are more
8 trademarks, in fact, than there are words in
9 the dictionary. So, you have to -- I
10 thought that was pretty -- pretty amazing,
11 you know, which is why you've got to get
12 creative people to do this stuff.

13 Now -- now, but these things here
14 are -- are what they say are -- are the
15 different categories of how you think about
16 it, you know, as you go about it as a team,
17 you know, association, different, clear,
18 pronounceable, memorable --

19 (Reporter clarification.)

20 THE WITNESS: The categories were
21 product association, different, clear,
22 pronounceable, memorable, positive and
23 available. All the categories that you
24 needed to -- you had to be able to have all
25 of these apply at the end of the day.

1 BY MR. HANSEN:

2 Q. And we may have discussed this already, but
3 why was it important -- why was it an
4 important metric for the name to be
5 different from the competition?

6 A. Because we had -- we have a novel,
7 first-in-the-world-ever-done product. We
8 want -- we wanted no confusion that this had
9 any similarity to anything else. It had to
10 be totally unique, the word, to imply the
11 fact that this also was a totally unique
12 product.

13 Q. If you turn to the slide just before the one
14 that we're on, there's an identification of
15 a number of products that treat pulmonary
16 conditions, correct?

17 A. Yes.

18 Q. Why were you considering these other
19 entities and names in this process?

20 A. Because we knew that these were names of
21 products that interventional cardiologists
22 were already familiar with and using, and we
23 wanted to make sure that ours was -- you
24 know, was not similar to any of them. I
25 mean, again, getting back to the different

1 and unique category.

2 Q. I think you said interventional

3 cardiologists --

4 A. Oh, did I say that?

5 Q. -- do you mean pulmonologists?

6 A. I continue to do that, because I used to be

7 one, but, yeah, interventional

8 pulmonologists. Glad Marty isn't here.

9 Q. If you turn to slide Holaira 56, it's
10 entitled: Naming Categories?

11 A. Yeah -- yes.

12 Q. Can you describe for me what -- what this
13 slide reflects and what these naming
14 categories mean?

15 A. Well, the way the marketing team helps
16 stimulate growth -- I mean, group-think is
17 to provide categories, you know, of
18 concepts, and they generally name, when
19 they -- you know, in doing this, they come
20 up with anatomic things or physiologic
21 things or structures, you know, that are --
22 that have something to do with what you're
23 doing, you know, and so, therefore, in terms
24 of what we do, it's -- it's pretty easy for
25 them to go nerve, air, pulmonary, lung,

1 respiration, open -- you know, "open"
2 meaning open airway.

3 So -- and then they -- and then you
4 take each of those one by one and start to
5 create words that might be related or convey
6 or be related to these general categories.

7 Q. So, for example, air-centric?

8 A. Yes.

9 Q. What -- what impact does a word being
10 air-centric have on the word itself?

11 A. Well, I mean, each of these would -- would
12 commonly -- you know, would -- you work
13 around that. You start with that concept
14 of, say, air, and then you work around it
15 and try to mold words, you know, that might
16 encompass it.

17 Q. Okay. And why -- if you know, why were
18 these specific categories identified as
19 potential categories for words?

20 A. Because they related -- they all had
21 something to do with our procedure, you
22 know, what we do.

23 Q. If you turn -- we're going to jump around
24 just a little bit, but if you turn to the
25 third from last page of the slide deck,

1 which is Holaira 111, there's a short list
2 of names.

3 Were there more names considered
4 than just this -- this short list?

5 A. Oh, yes, yeah, yeah. I mean, there were --
6 yeah, there were many, and in all of those
7 categories, there were a lot in each
8 category.

9 What these -- what these marketing
10 people do, they sit down and -- and they
11 provide you with a list to stimulate, you
12 know, all various renditions within these
13 categories.

14 Q. What -- what process was used to take the
15 longer list and winnow it down to the
16 shorter list?

17 A. We had -- we had a group meeting, where we
18 had -- there were really -- there were
19 really, you know, a smaller group of people,
20 four or five people, that -- that put the
21 most time into this.

22 It was myself; it was Marty Mayse;
23 it was Steve Dimmer, the other founder;
24 Lorraine Wright, we probably put in
25 relatively more time in discussion, but

1 there was also a larger group of some of the
2 other employees in the company that were
3 also brought in to comment on -- on just gut
4 reaction, you know -- you know, what kinds
5 of things that started to shake out as
6 people's favorites.

7 Q. Let's flip back in the slide deck to
8 Holaira 65, which is an air-centric name,
9 and the name is Holaira?

10 A. Yep.

11 Q. Ultimately, this is the name that the
12 company selected, right?

13 A. Yes.

14 Q. Why did the company select the name Holaira?

15 A. The -- there were -- there were several
16 reasons that this one, as more and more
17 discussion went, rose to the top, and the
18 one that I liked the best was that the
19 fundamental reason why I think our product
20 is going to be so exciting in the
21 marketplace is because the current standard
22 of care for this disease is -- are these
23 inhalers, these drugs, you know, that people
24 breathe -- breathe in, but what's known
25 by both -- all physicians know this, and the

1 pharmaceutical companies themselves
2 acknowledge it, is that the Achilles heel of
3 drugs that they don't talk about for
4 treating lung disease is that, when they
5 breathe these drugs in -- and they can only
6 be given by -- by inhalation. They can't be
7 given by swallowing pills, and there's
8 reasons for that pharmacologically, but the
9 drugs will go preferentially into those
10 small airways that are wide open, and they
11 won't go to the ones that are blocked, the
12 drugs.

13 So, the drugs, it's estimated,
14 achieve only maybe at best 50 percent of the
15 potential benefit that could be had if you
16 had a way to get -- get -- you know, get, in
17 effect, in all of the airways, not just the
18 open ones, but that's also not really known
19 for sure. People debate that.

20 Some people say it's less even, you
21 know, but -- so, drug therapy is really only
22 treating part of the lung, you know, when
23 these -- when it goes in, but it's still
24 better than nothing.

25 Our real benefit of our therapy by

1 going in and denervating the nerves in the
2 right and left mainstem bronchus, and 100
3 percent of all the nerves that go to the
4 lungs go in -- are in the walls of that
5 right and left mainstem bronchus. By
6 denervating, we could dilate all the
7 airways, the whole thing, the whole lung,
8 and so, I love the concept that we'll be the
9 first company that can truly deliver therapy
10 to the whole lung, you know, and so -- and,
11 whereas, I would say pharmaceuticals deliver
12 therapy to only part of the lung. We're the
13 whole lung.

14 And so, the whole focus here was on
15 whole, you know, W-H-O-L-E, but the
16 marketing people, being the clever way they
17 are, said, let's spell it H-O-L, because
18 it's pronounced exactly the same way and
19 it's clever. Now, you're looking like a
20 unique word, as opposed to W-H-O-L-E, which
21 is a word that everybody recognizes.

22 So, shorten it to Hol, H-O-L. So
23 air to the whole lung, and that really
24 started to resonate to people as really a --
25 a cool thing.

1 The second thing was that -- was
2 that, as the people started doing reviews,
3 there's very, very few things in all of
4 medicine, you know, whether it's drugs or
5 procedures or -- or words or anything that
6 begin with the letter H. H is really rare.
7 So, it was extremely unique, and the other
8 thing is is that we also found out the word
9 holo, H-O-L-O, is actually another word that
10 you can find out there, and actually its
11 derivation is also whole, you know,
12 actually. So, if you drop the W in -- you
13 know, in languages, H-O-L-O, also means
14 whole. So, it really came through that it
15 was air to the whole lung and -- and really
16 unique.

17 The one thing that -- that I had a
18 little hesitation about, which actually also
19 makes it -- made it really unique, but was
20 that we struggled with, and when we tested
21 this around with different people, people
22 had -- when they said, what do you think
23 when you see this word? Well, you know,
24 there's a derogatory street slang term
25 called ho, you know, like that person's a

1 ho.

2 Anyway, but that is a negative
3 term, and -- and so, we struggled with the
4 fact that it would have too strong, you
5 know, a differential, you know, in terms of
6 a word being thrown into -- into medicine,
7 and so -- but the marketing people actually
8 kind of liked that, because it gave it more
9 of an edge, you know, of uniqueness. And,
10 by the way, nobody really thinks that, you
11 know, as our testing -- they really see
12 "whole," you know, is where they go.

13 Q. Can you describe for me how the company
14 pronounces its name?

15 A. Yeah, it's Hol, H-O-L, hyphen, second
16 syllable, is air, A-I-R, and the last
17 syllable is A. Three syllable, where it's
18 H-O-L, then second syllable A-I-R, another
19 syllable A, and we really differentiated --
20 we really wanted that differentiated all the
21 way to the point that on the -- that, on the
22 logo, we put an umbrella of dots over the
23 word A-I-R to differentiate the word "air"
24 and separate it from the syllable H-O-L, so
25 there was no -- no -- to really call that

1 out, to get the word Hol on there, H-O-L,
2 and you've seen the -- it's on the business
3 cards. You've seen the logo.

4 Q. Going back to the -- the short list of -- of
5 names, there were -- at the back of the
6 slide deck, there are a number of names that
7 Holaira ultimately did not go with.

8 A. What page?

9 Q. 111?

10 A. Oh, 111.

11 Q. Yep. For example -- well, first, let me ask
12 you this: There are a number of names that
13 have Xs in the different columns.

14 A. Yeah.

15 Q. Would we take that to mean that the names
16 with Xs are in the running or out of the
17 running?

18 A. In the running.

19 Q. Why didn't Holaira end up using the name
20 Vitaira?

21 A. Well, you know, there were people that liked
22 Vitaira in the group, but -- but one of the
23 things that -- that became a differentiator
24 on that one was that, for whatever reason,
25 and these things tend to go in trends, but

1 if you look at the last four or five years
2 of medical device company names, there have
3 been a lot of Vs. There's a lot of
4 companies out there that start with V, and
5 so, for that reason, that was a
6 discriminating -- that was probably one of
7 the main reasons why we moved away from that
8 at the end of the day. In discussion, in
9 fact, my first company had begun with a V,
10 Velocimed, and that was a bias to me. I
11 didn't want to do another V company.

12 Q. And why didn't you select Apaira?

13 A. Again, I think that it was a -- there are A
14 companies out there, and we thought that --
15 we thought that there was another company
16 out there called Alero, you know, that we
17 thought that looked a little close to, so we
18 thought Apaira was close to some other
19 competitors.

20 Q. And when you say "Alero," are you talking
21 about the product sold by Boston Scientific?

22 A. No.

23 Q. What --

24 A. It's a pharma -- it's a pharma drug.

25 Q. And how do you spell that?

1 A. A-L-E-R-O, I think is the name of it -- is
2 how it's spelled.

3 Q. Ultimately, you went with one of the
4 air-centric names, Holaira?

5 A. Yes.

6 Q. Why did you go with an air-centric name?

7 A. It was a category people liked the best. I
8 mean, it is the fundamental basis of what we
9 do is to improve airflow to the lung. I
10 mean, it's -- it's the closest.

11 Q. Were you aware of any other company name,
12 product names or trademarks, that had the
13 word air within it when you made the
14 decision to go with an air-centric name?

15 A. Yes, there's a lot -- there's a lot of
16 "airs" out there.

17 Q. When you say "there's a lot of airs out
18 there," what do you mean?

19 A. I mean, there's a lot of companies -- I
20 mean, there's a lot of products out there
21 where the syllable A-I-R is a part of the
22 name.

23 Q. And what -- what field are those products?

24 MR. WALZ: Objection, foundation.

25 BY MR. HANSEN:

1 Q. Do you know -- you mentioned that there's a
2 lot of words out there with "air" in it?

3 A. Yes.

4 MR. WALZ: Objection, foundation.

5 MR. HANSEN: To what?

6 MR. WALZ: How does he know that
7 there are a lot of products out there that
8 have "air" in it? You can lay the
9 foundation. I don't know how he knows that.

10 MR. HANSEN: He just testified that
11 he knows it.

12 MR. WALZ: How do you know it?

13 BY MR. HANSEN:

14 Q. Okay. Dr. --

15 A. I've seen them a pulmonary meetings and
16 generally follow the literature.

17 Q. Okay. So, you work at a company that has a
18 product -- is developing a product in the
19 pulmonary space, correct?

20 A. Yes.

21 Q. And through going to meetings in the
22 pulmonary space, you're aware of other
23 company names?

24 A. And product names, yeah -- yes.

25 Q. And is that how you're aware of other --

1 A. Yes.

2 Q. -- names using the word "air"?

3 A. Yes.

4 Q. And are those other product names that are
5 in your mind in the pulmonary space?

6 A. Yes.

7 Q. Can you recall any of them?

8 A. Xolair.

9 Q. What does Xolair do?

10 A. It's a drug.

11 Q. What -- are you aware of the term "Alair"?

12 A. Yes.

13 Q. Sold by Boston Scientific?

14 A. Yes.

15 Q. Why -- what consideration, if any, did you
16 take of that name when deciding to choose
17 the name Holaira?

18 A. Say that again.

19 MR. WALZ: If I could, you took a
20 piece of paper out of your coat pocket, and
21 you now seem to be referring to it.

22 THE WITNESS: Yes, there's -- I
23 have four names of companies with "air" in
24 it that I think are really good examples.

25 MR. WALZ: Okay. That's fine. You

1 can use it.

2 THE WITNESS: Okay.

3 BY MR. HANSEN:

4 Q. Dr. Wahr, what -- what examples are on that
5 piece of paper?

6 A. Well, there's Singulair, Xolair, VitalAire
7 and Alere, A-L-E-R-E.

8 Q. Turning back to my question about Alair, the
9 product sold by Boston Scientific, what
10 consideration, if any, did you take of the
11 existence of that name when deciding to use
12 the name Holaira?

13 A. We wanted to make sure that we were very
14 different from any other word, and I would
15 say that that fell into that category. You
16 know, we were -- we -- as you saw in the
17 previous slide, we got the list of the other
18 leading -- or I shouldn't say leading, but
19 the known products that are used by
20 interventional pulmonologists, and so, we
21 looked at that entire list and said, are we
22 different than all of these words, you know,
23 and we were -- we were confident we were
24 different from all of these words, because
25 nobody had anything that looked like Hol,

1 H-O-L, at the beginning of the word.

2 Q. What -- why did you want to be different
3 from Alair?

4 A. Because eventually -- because we have a
5 unique product, and we want our -- our
6 physicians, who are our main customers,
7 to -- to have no confusion about what we are
8 doing.

9 Q. Let's turn to the -- the development of the
10 Holaira products.

11 I understand, and certainly tell me
12 if I'm wrong, I understand that the Holaira
13 product is not commercially available in the
14 United States?

15 A. It's a clinical stage company.

16 Q. When you say "it's a clinical stage
17 company," what do you mean?

18 A. It's not approved for use, you know, for
19 commercial sale.

20 Q. And what -- what process is the company
21 undertaking to become approved for
22 commercial sale?

23 A. We're doing a -- we're working through
24 clinical trials, you know, human clinical
25 trials, and the -- the process that -- that

1 we're doing is we're doing a three --
2 three-stage development program, which has
3 began with Phase 1 clinical trials. We
4 finished that.

5 We're in what are now called
6 Phase 2 clinical trials, and then if our
7 data looks good in the Phase 2 trials, we'll
8 move on to what's called Phase 3 clinical
9 trials, which would be the pivotal trial.
10 We're in the middle of Phase 2 right now.

11 Q. Why is the company undertaking that process?

12 A. Well, the product is -- because the product
13 is novel and has never been done before, you
14 need to be very careful, you know, as you
15 work your way through the development
16 process, that you make sure that -- that
17 your product is safe, first of all, and the
18 way that's done in the eyes of the
19 regulatory authorities is they will approve
20 you to treat a small number of patients.

21 You treat those patients in the
22 Phase 1 trial, and then if that looks good,
23 then they'll give you a larger number of
24 patients you can treat, which is basically
25 Phase 2 trials. If that data looks good,

1 and basically Phase 1 and -- Phase 1 trials
2 are really focused on safety. You know,
3 they -- the way this works, they first want
4 to know that you're not going to hurt
5 anybody, and then if they -- if you pass
6 that bar, then you move on to where your
7 trials will be big enough that you can start
8 to, in followup testing, show that you're
9 actually beneficial, you know, but safety
10 comes first, and then you move on to the
11 benefit part.

12 So, Phase 2 kind of attempts to
13 re-corroborate the safety issue of Phase 1
14 in a large enough pool of patients that you
15 might be able to start to get a signal to
16 understand your -- your efficacy of a mark.
17 The other thing -- the other part about
18 Phase 2 trials is that you also are allowed
19 to start exploring some other parameters,
20 such as dose and, you know, some other
21 variables about your product.

22 Q. You mentioned --

23 A. But when you get to Phase 3 -- when you get
24 to Phase 3, you need to have your final
25 procedure and your energy dose and

1 everything has to be defined and done, and
2 then that's it, and that would be the trial
3 in which eventual approvals are based is
4 Phase 3.

5 Q. You mentioned earlier that there are three
6 classes of products within the FDA?

7 A. Right.

8 Q. What class of product is the Holaira System?

9 A. It's Class 3, and generally Class 3 products
10 are the products where you would go through
11 this type of extensive clinical testing
12 program.

13 Class 1 products, for example, may
14 not need any clinical testing at all. I
15 mean, they could literally just -- in
16 humans, they could just be developed on a
17 benchtop somewhere and get approval.

18 Generally, Class 2 products are
19 somewhere in between. Generally, they
20 require a -- some human testing in a trial,
21 but for sure Class 3 products require, you
22 know, an extensive development program since
23 it's never been done before, and you've
24 really got to prove that safety thing
25 before -- before they're going to let it go

1 out on the market.

2 Q. What indication is being sought for the
3 Holaira products?

4 A. Patients of -- patients with moderate to
5 severe COPD.

6 Q. Let's turn now, Dr. Wahr, to the use of the
7 name Holaira.

8 When did -- when did the name
9 Holaira start being used by the company, if
10 you recall?

11 A. Probably in the first quarter, first quarter
12 of 2013. We -- yeah, plus or minus a month
13 or two, somewhere in there.

14 Q. And how is the -- how is the Holaira name --
15 how is the Holaira name used?

16 A. We use it -- I mean, it's the name of the
17 company. It's on the building. It's --
18 it's on our business cards. It's the name
19 on our Website, and it's -- and it's the
20 name on -- you know, on the product.

21 You know, I mean, it's the Holaira
22 Lung Denervation System. It's on the
23 console, and it's -- we use it on our slide
24 template -- our PowerPoint slide template
25 that we use when we present abstracts and

1 our scientific data. I mean, it's the name
2 of -- it's the name of the system and the
3 name of the company, so it's on that stuff.

4 Q. At what events, if any, has Holaira
5 presented to physicians?

6 A. Publicly, public presentations of our
7 company to date has only happened one time,
8 and that was -- our coming-out party for
9 public presentation was at the European
10 Respiratory Society meeting in Munich,
11 Germany last fall.

12 That's the only public
13 presentation, you know, at a -- at a trade
14 show, and we did not have a booth. It
15 was -- we were start of the scientific
16 agenda. We had abstracts that were accepted
17 for presentation, and we did one evening
18 symposium, you know, where we summarized our
19 product for the -- you know, for the
20 attendees.

21 Q. And what were the attendees? Who was the
22 audience at that --

23 A. Primarily interventional pulmonologists, as
24 well as, in general, pulmonologists. That
25 would -- that made up the majority of the

1 audience, and then there were industry
2 people there as well.

3 You know, whenever a new product is
4 kind of like shown at one of these meetings,
5 other companies that are in the space always
6 come out of interest as well, as you would
7 expect.

8 Q. When I asked a few questions ago, you made a
9 distinction, I think, between public and
10 private presentations?

11 A. Yes.

12 Q. Has the company done any private
13 presentations?

14 A. Yes. Oh, yes. I mean, everybody -- you
15 know, all of our physicians, who are
16 investigators in our clinical trials, you
17 know, obviously, have had private
18 presentations, and not only private
19 presentations, but have gone through
20 training, extensive training, on how to use
21 the device, and so, there's been meetings
22 with that group of doctors, but we also have
23 meetings with physicians in private that are
24 other key opinion leaders, KOLs, that stands
25 for key opinion leaders, leading physicians

1 in the interventional pulmonary space, to
2 get their feedback and input and, you know,
3 reaction to what we're doing.

4 So there's been a number of those
5 meetings as well.

6 Q. And in those meetings you use the name
7 Holaira?

8 A. Yes.

9 Q. Approximately how many private presentations
10 would you say that Holaira has had?

11 A. Over -- since I have been CEO, those types
12 of meetings, fairly formal meetings, I would
13 say at least 50.

14 Q. And are those to interventional
15 pulmonologists in the United States or
16 elsewhere?

17 A. Both Europe and the United States.

18 Q. And within the United States, how many of
19 those types of meetings have you had?

20 A. Probably about a third of them have been
21 with US docs; two-thirds of them with
22 European physicians.

23 Q. Has --

24 A. Our US -- our US -- we have no US clinical
25 sites yet. You know, we're hopeful we'll

1 have some later, you know, in the not too
2 distant future.

3 Q. Has Holaira used the name Holaira in any
4 press releases?

5 A. Yes.

6 Q. Do you know about how many in the last, what
7 is it, three and a half years?

8 A. Since I have been CEO, there have been five
9 press releases.

10 Q. What's the general topic of those press
11 releases, if you recall?

12 A. The majority of the -- most of them were
13 related to finance. It's common to do press
14 releases after you raise money successfully,
15 and -- or to announce, say, a key new
16 employee hire, and then I think one of them
17 was on -- you know, was announcing our
18 clinical data that was going to be shown at
19 the European Respiratory Society.

20 Q. Has Holaira --

21 A. They're -- they're all posted on the
22 Website.

23 Q. Has Holaira clinical data been published in
24 any medical journals?

25 A. Yes. Yeah, our Phase 1 -- our first

1 clinical trial now is published in a
2 peer-reviewed journal called Thorax.

3 Q. Has -- are you aware of any confusion
4 between Holaira and Alair?

5 A. None.

6 Q. Are you aware of any confusion between or
7 about Holaira's affiliation or lack of
8 affiliation with Boston Scientific?

9 A. None.

10 Q. Let's turn now, Dr. Wahr, to the sales
11 process for the Holaira product.

12 First, who is the -- the target
13 customer for the Holaira products?

14 A. The interventional pulmonologists.

15 Q. Why is that?

16 A. Because our product will -- will be labeled
17 that it is only for use by an interventional
18 pulmonologist. That will be -- and then
19 even if you are a Board-certified
20 pulmonologist, just that by itself is not
21 sufficient. You will also have to go
22 through and finish the formal training
23 program.

24 Q. I'll dig into the formal training program in
25 just a minute.

1 A. Okay.

2 Q. But you mentioned it will be labeled?

3 A. Yeah.

4 Q. What -- what does that mean, "it will be
5 labeled"?

6 A. Well, the -- the -- when the FDA approves a
7 product, they -- they define in the label
8 who the patients are that -- what are the --
9 what are the inclusion criteria that the
10 patient must have in order to be a candidate
11 for the therapy.

12 In our case, it would be moderate
13 to severe COPD, you know, and what the
14 testing parameters are that make that
15 patient formally eligible to get the
16 therapy; and, number two, what are -- what
17 are the requirements for a person to be --
18 to use the device.

19 You know, what is the training
20 qualifications, you know, for a person to be
21 able to use the device. Those are defined
22 as part of a product being approved by the
23 FDA.

24 Q. What -- what sales -- I understand the
25 product isn't commercially available as of

1 yet, but does the company have some sense as
2 to what sales process it intends to employ
3 when the product becomes commercially
4 available?

5 A. Yes. I mean, yes. I mean, we don't have a
6 detailed plan, because that's out there in
7 the future, you know, a number of years,
8 but -- but at a high level, yes, and our
9 plan for commercialization will be a direct
10 sales force.

11 Q. And what do you know by a direct sales
12 force?

13 A. Meaning --

14 Q. Can you describe that?

15 A. Meaning we will not use distributors or
16 other third-parties to -- to sell our
17 product.

18 Q. And how would the -- what's the concept of
19 how the direct sales force would go about
20 selling the product?

21 A. It would be -- it would be direct from -- I
22 mean, it would be direct to the
23 interventional pulmonologists. It would be
24 direct point-of-contact with the
25 interventional pulmonologists.

1 Q. You mentioned that that's a few years out.

2 Do you have an estimate as to how
3 far out that is?

4 A. The -- the --

5 Q. I should have asked a more clear question.

6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]

16 Q. You mentioned that training --

17 A. Yes.

18 Q. -- will be required to be able to use this
19 product?

20 A. Yes.

21 Q. What -- can you describe for me what that
22 training is?

23 A. Yes, the -- the training program, it isn't
24 just a training program for a commercial
25 product. The training program is also a

1 requirement even to just be doing our
2 clinical trials at this point in time, you
3 know, where we -- anybody who's going to be
4 an investigator for us has to go through the
5 formalized training program, which consists
6 of both didactic, where it's slide
7 presentations, you know, to instruct them in
8 every aspect of how to use both the console
9 and the device itself, you know, how to run
10 them, how to position them.

11 But there's also a -- you know, so,
12 there's a mechanical part to it, but there's
13 also an education about patient selection,
14 you know, entry criteria, you know, for
15 patients and also how the patients are
16 followed up afterwards. So, it's a
17 comprehensive, you know, all -- all parts of
18 it.

19 And in addition to the didactic
20 presentations, there's also a hands-on
21 training process, where -- where they use
22 the device on a mannequin, as well as on a
23 human cadaver, in a cadaver lab.

24 Q. And who provides this training to
25 physicians?

1 A. The company. We do, the company. You know,
2 our -- our technical team.

3 Q. Company employees?

4 A. Company employees, yeah.

5 Q. Is there any support provided by company
6 employees at actual patient cases?

7 A. Yes. After -- after completing the training
8 program, there is company support at all of
9 the clinical cases, 100 percent of them, and
10 when -- and we anticipate that that will go
11 on throughout the entire clinical program,
12 and the term they use for this is
13 proctoring, you know, in the medical world;
14 and there will be a requirement that comes
15 in at the time of approval by the FDA for
16 when the product goes commercial will be a
17 specific designation for how many cases
18 after completing the training program a
19 physician has to be proctored before he can
20 really be turned loose, you know, to just do
21 these cases in an unsupervised fashion.

22 And where that number is going to
23 be for the number of required proctored
24 cases, isn't settled yet. I mean we'll
25 learn more about that as -- as we go through

1 the whole clinical program, but I would
2 expect it will probably be in the
3 three-to-five-case range.

4 Q. How -- how, if at all, are patients targeted
5 for Holaira marketing?

6 A. We don't do any -- any -- any marketing to
7 patients, you know, at this point. Patients
8 have the potential to become aware of us,
9 you know, by finding -- you know, by
10 discovering it, you know, by reading
11 journals or going on the Website or things
12 like that, but we don't actively do any
13 marketing to patients.

14 Q. What is the -- does the company have a sense
15 as to what the price-point for the Holaira
16 System will be once it's commercially
17 available?

18 A. Well, it will be -- there's two components
19 to it. There would be the catheter, you
20 know, the dNerva catheter, will have --
21 which is a disposable, one-time use, and
22 will have one price; and then the console,
23 which can be used repeatedly, you know, on
24 many cases, will be another.

25 So, there will be two purchased

1 things; the console and the catheter. [REDACTED]

2 [REDACTED]

3 [REDACTED]

4 [REDACTED]

5 [REDACTED]

6 [REDACTED]

7 Q. Are you familiar -- in your time as an
8 interventional cardiologist, and as well as
9 based on your experience selling Class 3
10 medical devices, are you familiar with the
11 process for purchasing Class 3 medical
12 devices?

13 A. In hospitals?

14 Q. Correct.

15 A. Yes.

16 Q. What -- who makes the decision to purchase a
17 Class 3 medical device?

18 A. Hospitals have what's called a purchasing
19 department, and the purchasing department is
20 really the one that -- they issue the
21 checks. I mean, that's where -- that's the
22 key thing you got to get past, and they have
23 formalized processes for how they make the
24 decisions.

25 And, in general, the process starts

1 when a physician tells the purchasing
2 department that there's a new product, or in
3 some cases, the product's been around, but
4 just hasn't been there on -- you know,
5 available before, a physician makes a
6 request that they would like to have a
7 product, you know, put in the inventory or
8 on the shelf, so to speak, at the hospital.

9 And then when that happens, a
10 process starts in the purchasing department,
11 where -- where it's basically an application
12 process where you have to educate the
13 purchasing department about what it is, what
14 its merits are, you know, what its potential
15 benefits are, you know, to the patient.

16 It's usually initiated by -- it can
17 be initiated by any one of the physician,
18 you know, specialties in the hospital.
19 Generally purchasing departments then
20 consider other things. They might -- they
21 might ask for feedback from other
22 specialties that would know about this.
23 They -- they would -- they may look for
24 medical society recommendations. They
25 would -- they also would look very carefully

1 about whether there's reimbursement
2 available.

3 Sometimes hospitals will decide
4 this is a great product, but because no
5 reimbursement is available from the
6 insurance companies, they still won't put it
7 on the shelf. You know -- you know, and
8 that's when it sometimes comes into
9 conflict, you know, hospital -- I mean,
10 physicians versus hospitals that -- you
11 know, if the physicians want it, and the
12 hospital doesn't want to buy it, those are
13 interesting discussions, but it's a pretty
14 involved process.

15 Q. And why does the direct sales force -- or
16 why is the intent for the direct sales force
17 at Holaira to work directly with
18 interventional pulmonologists as opposed to
19 the purchasing department?

20 A. It's both a combination of the complexity of
21 the product, plus the cost, and -- and
22 that's too much to really rely on a
23 distributor for.

24 You know, distributors are
25 really -- in my experience, do best with

1 commodity-type products, you know, that
2 don't require education. You know, like for
3 example, if you had a -- there's 30
4 different hip prostheses out on the market,
5 and they're very -- and in many cases very
6 hard to differentiate one from another. You
7 know, a company might give a distributor,
8 here's our hip prostheses, go out there and
9 sell it, and -- because it's not a technical
10 sale, and if -- but as products get more and
11 more sophisticated, it's a -- you need your
12 own highly, highly educated company
13 representative to go in there and -- and
14 educate -- you know, educate that physician,
15 and then the hospital too.

16 I mean, you know, the company reps
17 get involved in the -- in the education part
18 even working with the purchasing departments
19 as well.

20 Q. And what -- what role does the physician
21 have in the decision to purchase the
22 product?

23 A. He is a -- he makes a recommendation, but
24 his recommendation is essential to starting
25 the process. I don't know of any situation

1 where a hospital purchasing department would
2 just, on their own, decide they want to put
3 something on the shelf. That wouldn't
4 happen.

5 Q. With a Class 3 medical device, is it
6 possible for a patient to purchase the
7 product?

8 A. No.

9 Q. Why not?

10 A. It can't be sold. It's not for sale to --
11 to patients. It's for sale only to -- to
12 the hospital's purchasing department on the
13 recommendation, you know, of the
14 pulmonologist.

15 Q. How would a patient who comes across the
16 Holaira name, once the product's
17 commercially available, how would that
18 patient possibly get the treatment?

19 A. They would have to -- they would have to
20 identify a hospital and physician that --
21 that are approved to do the procedure and go
22 to that medical center.

23 MR. HANSEN: Why don't we go off
24 the record. I'll go through my notes and
25 see if I have any other questions for you,

1 Dr. Wahr.

2 THE WITNESS: Okay.

3 (Break taken.)

4 MR. HANSEN: Dr. Wahr, I have no
5 further questions for you at this time.

6 Thank you.

7 Do you want to take a break,
8 or do you want to --

9 MR. WALZ: Yeah, if we can take a
10 break, and I can just kind of get some docs
11 ready, and then we'll come back.

12 (Break taken.)

13 EXAMINATION

14 BY MR. WALZ:

15 Q. Dr. Wahr, are you ready?

16 A. Yes.

17 Q. Okay.

18 MR. WALZ: I'll just have you mark
19 this first.

20 (Exhibit Number 3 was marked.)

21 BY MR. WALZ:

22 Q. So, Dr. Wahr, you've been handed what's been
23 marked as Deposition Exhibit Number 3. This
24 was a document produced by Holaira.

25 Do you recognize that document?

- 1 A. Yes.
- 2 Q. And if we turn to page -- well, it's
- 3 Bate-numbered 1392?
- 4 A. Yes.
- 5 Q. At the bottom there, there's -- next to
- 6 signature, Dennis W. Wahr; is that correct?
- 7 A. Yes.
- 8 Q. And that is your signature?
- 9 A. Yes.
- 10 Q. And --
- 11 A. Well, I don't see a signature, but it's my
- 12 name typed.
- 13 Q. That's an electronic signature, correct?
- 14 A. Oh, okay. All right.
- 15 Q. And you signed this application, correct?
- 16 A. I -- I probably did, yes. It's three years
- 17 ago.
- 18 Q. So, it's possible that someone else signed
- 19 this application?
- 20 A. No, I just don't see my signature on here.
- 21 MR. HANSEN: Objection to the form.
- 22 THE WITNESS: No. Yeah, so, you
- 23 know, I mean I'm taking your word for it
- 24 that somebody printed this up with numbers.
- 25 BY MR. WALZ:

1 Q. Right. And you reviewed this application
2 before you signed it, correct?

3 A. Yes.

4 Q. And you understood what you were applying
5 for when you sign the application, correct?

6 A. Yes.

7 Q. And all the information in this application
8 was correct as of December 19th, 2012 when
9 the application was signed, correct?

10 A. I haven't -- it's been a long time since
11 I've read it, but I assume it was.

12 Q. So, if we look at the -- let's see here, if
13 we look at the page Bate-numbered 1391?

14 A. Yes.

15 Q. You will see, next to International Class
16 10, there's a description that reads:
17 Medical devices, medical apparatus and
18 instruments?

19 A. Yes.

20 Q. Now, that identification was at some point
21 amended; is that correct?

22 A. I don't know if we amended this or not. I
23 don't know the answer to that.

24 Q. Okay.

25 A. I don't understand your question.

1 (Exhibit Number 4 was marked.)

2 BY MR. WALZ:

3 Q. So, you've been handed what's been marked as
4 Deposition Exhibit Number 4. This is a
5 printout from the United States Patent and
6 Trademark Office test database, and next to
7 the Goods and Services heading, there's a
8 description that reads: Medical devices for
9 treating obstructive lung diseases; medical
10 apparatus and instruments for treating
11 obstructive lung diseases.

12 Do you see that?

13 A. Yes.

14 Q. And that's different from the description we
15 saw on Exhibit 3, correct?

16 A. In that paragraph that starts,
17 "International Class;" you're referring to?

18 Q. Correct, on Exhibit Number 3.

19 A. Well, it's -- I mean, the wording is
20 slightly different, but it's saying the same
21 thing. I mean, it's -- it's a device for
22 treating obstructive -- it's a medical
23 apparatus and instrument. The one -- the
24 one on the right is -- looks like it's more
25 detailed.

1 Q. And when you say "the right," you're
2 referring to Exhibit Number 4, correct?

3 A. Right.

4 Q. And looking at Exhibit Number 4, does that
5 description accurately reflect the device
6 that will be used in connection with the
7 Holaira mark?

8 A. Yes, this is appropriate.

9 Q. Okay. And you have no intention of further
10 amending or clarifying the identification
11 description that you see in Exhibit
12 Number 4, correct?

13 A. Not at this point in time.

14 Q. Okay. And just for a purpose of clarity, I
15 think when you were discussing before the
16 difference between dNerva -- the mark
17 dNerva --

18 A. Yes.

19 Q. -- and the Holaira mark, you mentioned that
20 dNerva will be used as the product name, but
21 that Holaira is going to be the company
22 name?

23 A. Holaira -- Holaira is the company name. The
24 system, you know, the whole system that
25 consists of the console, you know, and the

1 catheter, we call the Holaira Lung
2 Denervation System.

3 Q. Okay.

4 A. But the catheter, the catheter that's
5 disposable, the part that goes through the
6 bronchoscope, is the dNerva catheter.

7 Q. I see, okay.

8 (Exhibit number 5 was marked.)

9 BY MR. WALZ:

10 Q. So, you have been handed what's been marked
11 as Deposition Exhibit Number 5.

12 Do you recognize this document?

13 A. Yes.

14 MR. HANSEN: I'll just object it's
15 outside the scope of the direct examination.

16 MR. WALZ: We'll bring it within
17 the scope.

18 THE WITNESS: Yes.

19 BY MR. WALZ:

20 Q. You do recognize it? Okay.

21 And if we flip to the second to the
22 last page again at the bottom, we see next
23 to signature, Dennis Wahr?

24 A. Yes.

25 Q. That is your signature?

1 A. Yes.

2 Q. And you did sign this application as well?

3 A. Yes.

4 Q. Okay. And then if we look on the third page
5 from the end, next to Class 10, we see
6 medical devices, medical apparatus and
7 instruments, correct?

8 A. Yes.

9 (Exhibit Number 6 was marked.)

10 BY MR. WALZ:

11 Q. So, you have been handed what's been marked
12 as Deposition Exhibit Number 6. This is a
13 printout from the United States Patent and
14 Trademark Office test database. It's for
15 the dNerva mark, and, again, next to the
16 heading Goods and Services, we see medical
17 devices for treating obstructive lung
18 diseases; medical apparatus and instruments
19 for treating obstructive lung diseases?

20 A. Yes.

21 MR. HANSEN: Objection, outside of
22 the scope of the direct examination.

23 BY MR. WALZ:

24 Q. And similar to the Holaira mark we saw
25 before, comparing the Exhibit 6 to

1 Exhibit 5, the description was amended,
2 correct, to what appears on Exhibit 6?

3 MR. HANSEN: Same objection.

4 You can answer.

5 THE WITNESS: Okay. The words on
6 the -- on the Exhibit 6 are -- are slightly
7 different than here, but, again, it appears
8 like they're saying the same thing.

9 BY MR. WALZ:

10 Q. And if we compare Exhibit 6 with, I
11 believe -- what was the Holaira -- I can't
12 remember the number -- test page? So, is
13 that Exhibit 4?

14 A. 4.

15 Q. So, if we compare what's in Exhibit -- the
16 identification in Exhibit 6 with the
17 identification of the goods description in
18 Exhibit 4, those descriptions are the same?

19 A. They look the same.

20 MR. HANSEN: Same objection.

21 BY MR. WALZ:

22 Q. Okay. And if you look at Exhibit 1 --

23 MR. HANSEN: Do you mean Exhibit 3,
24 Brad?

25 MR. WALZ: I'm sorry, Exhibit 3.

1 BY MR. WALZ:

2 Q. If we look at the page that's numbered 1391,
3 underneath that International Class 10,
4 there's an Intent to Use, and it says: The
5 applicant has a bona fide intention to use
6 the -- or use through an applicant's related
7 company or licensee the mark in commerce or
8 in connection with the identified -- on or
9 in connection with the identified goods or
10 services.

11 Do you see that?

12 A. Yes.

13 Q. And at the time you signed this application,
14 you had the present intent to use the
15 Holaira mark in connection with a medical
16 device for treating obstructive lung
17 diseases, medical apparatus and instruments
18 for treating obstructive lung diseases,
19 correct?

20 A. Yes, after going through all the appropriate
21 regulatory approvals.

22 Q. Right.

23 A. Yeah.

24 Q. And after -- if we look at Exhibit 5, that's
25 the dNerva application, looking on page --

1 page 4, under that International Class 10,
2 we have that same "intent to use" language?

3 MR. HANSEN: Object, outside the
4 scope.

5 You can answer.

6 THE WITNESS: Yes.

7 BY MR. WALZ:

8 Q. And the dNerva application was filed, if we
9 look at the second to the last page -- or
10 was signed, I should say, on April 25th,
11 2013, correct?

12 A. Yes.

13 Q. And then if we look at Exhibit 6, and we
14 look at the filing date, it was actually
15 filed the same day as well, correct?

16 A. Yes.

17 Q. And that's approximately four months after
18 the Holaira application, which is Exhibit 3,
19 was signed by you, correct?

20 A. Yes.

21 Q. So, my question is: How could you have a
22 bona fide intent to use the Holaira mark if
23 four months later you filed an application
24 for the dNerva mark with the exact
25 identification of goods descriptions?

1 A. Well, the -- we decided that we wanted a
2 distinct name for -- for the actual catheter
3 itself versus the system, and so, we wanted
4 one more -- we wanted a different -- it's
5 different parts of -- it's a specific part
6 of the bigger system.

7 You know, the system is the Holaira
8 Lung Denervation System, but the disposable
9 product is its own entity. It's different.

10 Q. So, is the dNerva application, the ID in
11 that dNerva application, misdescriptive of
12 the goods that will actually be used in
13 connection with the mark?

14 MR. HANSEN: Object to form and
15 outside the scope.

16 BY MR. WALZ:

17 Q. I guess I'm trying to find out if one of
18 these applications is misdescriptive of --
19 of what you intend to use the mark for?

20 A. Well, the -- the description is general. I
21 mean, they both apply. I mean, it's
22 accurate for both. It's a correct
23 designation for both -- both marks.

24 Q. But you said dNerva would be used in
25 connection with the disposable catheter, not

1 a medical device for treating obstructive
2 lung diseases?

3 A. Well --

4 MR. HANSEN: Object to the form.

5 THE WITNESS: Well, the catheter is
6 part of the system. So, it would be used in
7 the same way, and you're confusing me. I'm
8 not sure where you're going with that.

9 BY MR. WALZ:

10 Q. That's okay. We can move on.

11 A. Okay.

12 Q. So, the Holaira device can be used to treat
13 chronic asthma, correct?

14 A. In theory, if we -- if we chose to go that
15 way, in theory, it could, yes. It would be
16 a completely new clinical development
17 program.

18 Q. And that is an area that you're thinking of
19 expanding into, correct?

20 A. Not right now.

21 Q. But it is something that you have --

22 A. It's theoretically possible that we could
23 make that decision at some point in the
24 future.

25 Q. Right. But you've promoted that to

1 potential investors and -- and identified it
2 as a potential area?

3 A. Yes.

4 Q. And you market -- as you testified, you
5 market the device to physicians, right,
6 interventional pulmonologists?

7 A. Interventional pulmonologists.

8 Q. Okay. And you're marketing that as a
9 treatment for COPD, correct?

10 A. Correct.

11 Q. And that term is understood as an umbrella
12 term, right?

13 A. COPD, yes.

14 Q. And so, under that umbrella, would include a
15 condition such as chronic asthma, correct?

16 A. No. COPD is generally -- is generally felt
17 to have two major components. One would be
18 emphysema, and the other would be chronic
19 bronchitis.

20 Asthma is a -- is felt to be a
21 distinct different disease process. We --
22 we do not believe that -- we certainly
23 believe that asthma does not fall under our
24 label indications.

25 MR. WALZ: Okay. Would you mark

1 that as 7, I believe.

2 (Exhibit Number 7 was marked.)

3 BY MR. WALZ:

4 Q. So, you've been handed what's been marked as
5 Deposition Exhibit Number 7. It is a
6 printout from the
7 medical-dictionary.thefreedictionary.com.
8 These are definitions concerning COPD.

9 If you turn to page 5, and I guess
10 it flows over into page 6, and if you look
11 at page 6 first, this is -- well, the
12 definition that begins on page 5 for COPD
13 that turns over -- or spills over onto page
14 6 at the bottom, this is a definition from
15 McGraw-Hill Concise Dictionary of Modern
16 Medicine.

17 Do you see that at the bottom?

18 A. Yes.

19 MR. HANSEN: I'll object to the
20 document as containing hearsay.

21 BY MR. WALZ:

22 Q. So, if you turn to the first page -- or on
23 page 5, that final dictionary definition for
24 COPD states: Chronic Obstructive Pulmonary
25 Disease, Pulmonology, an umbrella term for a

1 group of usually progressive lung disorders
2 with overlapping signs and symptoms,
3 including asthma.

4 Do you see that?

5 MR. HANSEN: Object, hearsay,
6 foundation.

7 THE WITNESS: I'm not sure what
8 page -- I can't seem to find the page you're
9 on.

10 BY MR. WALZ:

11 Q. So, at the top of each page, there are page
12 numbers; do you see that?

13 A. Oh, okay. What page?

14 Q. Page 5, and that definition begins at the
15 bottom and spills over.

16 So, I was saying, do you see on
17 page 5, that last definition of COPD?

18 A. Yes.

19 MR. HANSEN: Same objections.

20 BY MR. WALZ:

21 Q. And it says: Chronic Obstructive Pulmonary
22 Disease, Pulmonology, an umbrella term for a
23 group of usually progressive lung disorders
24 with overlapping signs and symptoms,
25 including asthma?

1 MR. HANSEN: Same objection.

2 BY MR. WALZ:

3 Q. Do you see that?

4 A. Yes.

5 Q. Okay. And then if we turn to page 6, we see
6 another definition of COPD at the bottom.

7 This is from the Gale Encyclopedia of
8 Medicine, and it says: A term used to
9 describe chronic lung diseases, like chronic
10 bronchitis, emphysema and asthma?

11 MR. HANSEN: Same objections.

12 BY MR. WALZ:

13 Q. Do you see that?

14 A. Yes.

15 Q. Do you have any reason to dispute these
16 definitions?

17 A. I think that our -- our definition of
18 Chronic Obstructive Pulmonary Disease is
19 what we -- our indications on our labelling
20 indication are for chronic bronchitis and
21 emphysema. Asthma is excluded. We don't
22 treat asthma.

23 Q. Okay. But a doctor would understand, or a
24 physician would understand, the term "COPD"
25 according to these medical dictionary

1 definitions to include asthma?

2 MR. HANSEN: Objection, form,
3 foundation and hearsay.

4 THE WITNESS: No, I don't agree.

5 BY MR. WALZ:

6 Q. But the Holaira System will compete with the
7 Alair System; is that correct?

8 A. No, it will not.

9 Q. You said though that the Holaira System
10 could possibly treat asthma?

11 A. We have no clinical development program for
12 asthma, and every pulmonologist, as well as
13 interventional pulmonologist, sees them as
14 distinctly different diseases, and the only
15 way we could treat asthma would be if we
16 started over from scratch with a completely
17 new Phase 1, you know, feasibility study in
18 asthma patients, which, at this point, there
19 has been nothing initiated to start such a
20 program. It would be unaffordable for us to
21 do that.

22 Q. To start --

23 A. An asthma program.

24 Q. -- an asthma program?

25 A. Yes.

1 Q. But you are marketing that to your investors
2 as a potential area of growth, correct?

3 A. If -- in the future, if a new -- if a new --
4 if another company were to buy Holaira, they
5 could make a decision to start an asthma
6 program in theory, but understand that it
7 would be going all the way back to the
8 starting point and starting at point 0 in
9 terms of that, and -- and the earliest
10 commercialization date for us to have a
11 label indication for asthma, if somebody
12 wanted to start that today, might be 2025.

13 I mean, it's way out there, and it
14 would be another \$100 million development
15 program, which has not started at this
16 point.

17 (Exhibit Number 8 was marked.)

18 BY MR. WALZ:

19 Q. Showing you what's been marked as Deposition
20 Exhibit Number 8.

21 Do you recognize this document?

22 A. Yes, yes.

23 Q. And what is this?

24 A. This is a presentation that I gave at the
25 Piper Jaffray Healthcare Conference.

1 Q. So, if you turn to page 2, in the heading,
2 it says: Holaira, Treatment For COPD and
3 Asthma, right?

4 A. Yes, yes.

5 Q. Okay. And if we look at page 11, it's
6 Bates-numbered 12 --

7 A. Yes.

8 Q. -- we see a -- a chart of revenue
9 projections, and then at the bottom of that
10 chart, there's a box?

11 A. Yes.

12 Q. And it says: COPD and asthma indication
13 split 70/30 in 2022?

14 A. Yes.

15 Q. And then if we turn to page 12,
16 Bates-numbered 13, and again we see at the
17 top in the heading, this is a competitive
18 landscape, and in the chart, there is, in
19 the second box below company product,
20 Holaira, and then if we go to the right
21 under COPD, there's a checkmark; under
22 asthma, there's a checkmark; and under
23 emphysema, there's a checkmark.

24 Do those checkmarks indicate that
25 the Holaira device can be used --

- 1 A. Yes.
- 2 Q. -- to treat these conditions?
- 3 A. Yes, it could, yes.
- 4 Q. And then if we move below the Holaira box,
- 5 there's an entry for BSC that says, formerly
- 6 Asthmatx/Alair; and under that, we see a
- 7 checkmark in asthma?
- 8 A. Yes.
- 9 Q. And that indicates that the Alair System is
- 10 used to treat asthma, correct?
- 11 A. Yes.
- 12 Q. And Boston Scientific is identified on a
- 13 chart where you've labeled it competitive
- 14 landscape as a competitor, correct?
- 15 A. Yes.
- 16 Q. And if we turn to the very last page -- I'm
- 17 sorry, page 17, Bates-labelled 18, we see a
- 18 slide labeled -- titled: Series D Financing
- 19 Highlights -- I'm sorry, are you there?
- 20 A. Yeah, I know it. Go ahead.
- 21 Q. And underneath the bullet point, Milestones
- 22 Through 2016, there's a subpoint for asthma
- 23 as part of the clinical heading?
- 24 A. Yes.
- 25 Q. And that there's six months of data from the

1 asthma feasibility study.

2 Does this mean that you've already
3 started a feasibility study for the use --
4 use of the Holaira device to treat asthma?

5 A. No, this was -- this was a slide done,
6 because at the time we were raising our
7 \$40 million, we did not have an asthma
8 program. We wanted to leave open the
9 possibility that if one of our investors --
10 if our lead investor wanted us to start one,
11 that's when this could be available, but, in
12 fact, when we closed the \$40 million
13 financing, our new investors did not want to
14 do an asthma program.

15 So, therefore, this has completely
16 dropped off the radar screen, if that makes
17 sense to you.

18 Q. Yep.

19 A. So, our clinical program is emphysema and
20 chronic bronchitis.

21 Q. Let's talk a little bit about targeted lung
22 denervation.

23 So, I think, as you testified
24 before, targeted lung denervation, TLD, is
25 the generic name that you have created for

1 your procedure, correct?

2 A. Yes.

3 Q. And that's similar to what, you know,
4 Boston Scientific had done with bronchial
5 thermoplasty?

6 A. Exactly.

7 Q. And TLD is a procedure that will require a
8 patient's informed consent, right?

9 A. Yes.

10 Q. And with respect to the informed consent
11 obligations, one of the things that will
12 have to be discussed is the nature of the
13 procedure, correct?

14 A. Yes.

15 Q. So, as you described before, the use of a
16 bronchoscope, the use of a catheter to place
17 a energy emitter within the main bronchi,
18 and then the administration of energy in
19 that main bronchi, correct?

20 A. Correct.

21 Q. And there will have to be a discussion with
22 the patient that the Holaira device will be
23 used as part of that TLD treatment?

24 A. Absolutely.

25 Q. And in discussing the nature of the

1 procedure, you'll also have to explain to
2 the patient -- or the doctor will, I should
3 say, that, as you described, the treatment
4 is intended to denervate the nerves, that it
5 will not have -- it's not intended to avoid
6 any of the smooth muscle of the bronchi,
7 correct?

8 A. Yes.

9 Q. And, in fact, there is no effect to the
10 smooth muscle through targeted lung
11 denervation, correct?

12 A. That -- that's what we believe, yeah.

13 Q. So, then you will have to discuss the risk
14 and benefits with -- or the physician will,
15 with respect to TLD, and you'll also have to
16 discuss any alternatives, correct?

17 A. Yes, yes.

18 Q. And an alternative would be bronchial
19 thermoplasty?

20 A. For what we do? No, bronchial thermoplasty
21 is not indicated for COPD -- I mean, for
22 chronic bronchitis or emphysema.

23 Q. But that -- so, bronchial thermoplasty,
24 though, has an effect on the smooth muscle
25 tissue?

1 A. Yes.

2 Q. And --

3 A. That's what they say, yes.

4 Q. And we talked about how COPD is an umbrella
5 term, and that chronic asthma is underneath
6 that umbrella?

7 A. You -- you've completely manufactured that.
8 No interventional pulmonologist buckets
9 asthma with emphysema or chronic bronchitis.
10 Those are -- the two things that we treat
11 are completely different from asthma period.
12 That's why we have them in the three
13 columns. Boston cannot -- is not an label
14 to treat chronic bronchitis or emphysema.

15 Q. But there are variations to asthma, isn't
16 there? You can have acute asthma?

17 A. There -- there is a classification of
18 asthma, where -- where, in the severest
19 form, some of the pulmonologists will say
20 that it starts to look like COPD, but -- but
21 those are not -- those patients are not
22 included in our protocol or will be
23 on-label.

24 Q. So, a patient --

25 A. They're different.

1 Q. But a patient with chronic asthma, though,
2 if they were to talk to a physician about
3 TLD, a physician would have to have a
4 discussion at least about what treatment is
5 available for asthma, correct?

6 A. No, because there's --

7 MR. HANSEN: Object to form.

8 THE WITNESS: -- there's no label
9 indication for what we do.

10 BY MR. WALZ:

11 Q. Is there ever any operable use?

12 A. Huh?

13 Q. Does operable use happen at all?

14 A. It never -- it never happens with a
15 non-commercially-approved product. [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 Q. Oh, right, obviously. We're not -- yeah,
19 right, I guess, yeah, to bring --

20 A. I mean, if they want to go to jail, they can
21 do that if they want.

22 Q. Yeah, we're talking about a product that is
23 not yet commercialized, right?

24 A. Right.

25 Q. We're talking about an intent to use

1 trademark application.

2 So, just so I understand, as part
3 of a -- of a doctor's informed consent
4 obligation, you're saying that a patient
5 that they're advising with respect -- that
6 has chronic asthma would not have to be told
7 that, in addition to targeted lung
8 denervation, which could be used to treat
9 their condition, there's a separate
10 procedure called bronchial thermoplasty,
11 which could be an alternative to targeted
12 lung denervation?

13 MR. HANSEN: Object to the form,
14 lack of foundation.

15 THE WITNESS: Absolutely not.
16 You're really mixed up on this. You know,
17 the -- an asthma patient under any
18 circumstances, no doctor in the world would
19 tell an asthma -- would tell an asthma
20 patient that TLD is an alternative therapy
21 for what they have.

22 TLD at this point is an
23 experimental therapy only being tested in
24 chronic bronchitis and emphysema that, [REDACTED]
25 [REDACTED] they will get an approval, and

1 there's nothing even in the works.

2 They would have absolutely no
3 obligation to tell a patient that.

4 BY MR. WALZ:

5 Q. Okay.

6 A. And even if they did, it would be totally
7 unavailable.

8 Q. Okay. So, what -- yeah, I guess, again,
9 we're talking -- again, you're not using the
10 mark -- the device -- so, I'm not talking
11 about -- we need to think about in terms of
12 when your product is actually available and
13 gets approval, [REDACTED]

14 A. Right.

15 Q. So, when you're both in the market --

16 A. [REDACTED]

17 Q. [REDACTED] So, the two treatments are now
18 actually available.

19 TLD is available to persons?

20 A. For asthma -- I mean, excuse me, TLD for
21 chronic bronchitis and emphysema, right?

22 Q. COPD, right?

23 A. No.

24 Q. That's --

25 A. No, if you are choosing to arbitrarily use

1 COPD as this higher bucket, like your thing
2 says, then -- then it's an inappropriate
3 umbrella, because we are only going to be
4 approved for emphysema and chronic
5 bronchitis.

6 (Exhibit Number 9 was marked.)

7 BY MR. WALZ:

8 Q. Handing you what's been marked as Deposition
9 Exhibit 9.

10 If you turn to the second page?

11 A. Yep.

12 Q. This is -- it's titled: Six Degrees
13 Confidential Backgrounder.

14 Do you recognize this document?

15 A. What's the date of this one? October 12.

16 Yeah, this one would have been created about
17 a week after I started, but I recognize a
18 lot of the things in here. I'm not sure
19 I've seen this before, but go ahead.

20 Q. Okay. So, if we look at just even the
21 executive summary, and this was -- let me
22 back up.

23 I mean, the intent of this document
24 was to educate Six Degrees, who was your
25 marketing firm that was retained to help you

1 with the naming process, right --

2 A. Yes.

3 Q. -- to understand your company?

4 A. Yes.

5 Q. Okay. So, in the executive summary, there,

6 it says that: IPS is a system -- the main

7 objective of the IPS System is the

8 development of a commercial product to

9 enable a new therapeutic procedure, TLD,

10 which will improve respiratory function for

11 moderate to severe COPD patients?

12 A. Yes.

13 Q. And it doesn't say chronic bronchitis or

14 emphysema, correct?

15 A. You know --

16 MR. HANSEN: Feel free to review

17 the entire document before you answer

18 questions about it.

19 THE WITNESS: Yeah, I think you're

20 taking this out of context. Our COPD

21 definition that we use throughout the entire

22 company is COPD is chronic bronchitis and

23 emphysema. It is not asthma. Our clinical

24 programs, you know, make it clear that

25 asthma is not included.

1 But, by the way, could our device
2 eventually at some point be used to treat
3 asthma? The answer is yes, and I've said
4 that already, but we're not developing it
5 for that. So, that's the answer to your
6 question.

7 You know, so --

8 BY MR. WALZ:

9 Q. Okay.

10 A. -- I mean, you're arguing over the semantics
11 of this, but I can promise you, in
12 interventional pulmonology, we can bring in
13 20 experts, and they all see asthma,
14 chronic bronchitis and emphysema as three
15 completely different entities.

16 Now, most people traditionally
17 would put just two of them under COPD,
18 chronic bronchitis and -- chronic bronchitis
19 and emphysema under COPD. That's what you
20 see under every commercial on TV when you
21 see Spiriva advertised. And they put asthma
22 over here in a different category, because
23 its mechanism of action is different, and
24 it's a different disease process.

25 Q. Right.

1 A. And -- and that's -- that's how we use it,
2 but the point is is that I'm not denying the
3 fact that, if we ever -- if a future owner
4 or investor or something wanted to start an
5 asthma program, our device could -- could do
6 that, and that's why it appears in there.
7 I'm just simply saying we're not doing that
8 right now.

9 Q. Right.

10 A. And -- and if somebody decided to do it, it
11 would be way out there.

12 Q. Okay.

13 A. And I don't understand what that has to do
14 with the trademark anyway.

15 Q. Yeah, this is just -- this is just -- you
16 know, in all of the documents I've seen
17 produced by Holaira --

18 A. Yeah.

19 Q. -- reference is always made to COPD. So,
20 that's why I just wanted to get some
21 clarification as, you know -- and you even
22 describe it on your Website as an umbrella
23 term?

24 A. Over --

25 Q. So --

1 A. -- over CO -- over emphysema and chronic
2 bronchitis, yes.

3 Q. But as we saw in some of those medical
4 definitions, you know, asthma has been
5 included as -- under the umbrella?

6 A. I will go on the record though as the vast
7 majority of people in this space of the
8 experts separate asthma under a completely
9 separate umbrella and not under the COPD
10 umbrella. That's my statement, but it
11 doesn't matter to this anyways.

12 Q. That's your opinion, right?

13 A. Right, it's my opinion, and it's clearly
14 the -- the opinion of the vast majority of
15 people that this is how they would classify
16 it.

17 (Exhibit Number 11 was marked.)

18 BY MR. WALZ:

19 Q. So, you have been handed what's been marked
20 as Exhibit 11. This is an email from
21 Mark Laverman to Lorraine and also yourself.
22 You are identified as a recipient, and this
23 email attached two PowerPoint presentations.

24 One is the messaging blueprint, and
25 the second is the -- the naming -- what is

1 it called? Is it the naming concept?

2 So, you previously testified that
3 you were targeting only interventional
4 pulmonologists with respect to your sales
5 efforts?

6 A. It was the primary target.

7 Q. So, it's not the only target?

8 A. It's not the only target.

9 Q. Okay. What are some of the other targets?

10 A. Well, if you're putting -- if you wear my
11 hat as the CEO, my primary targets are,
12 number one, the customer, which is
13 interventional pulmonologists. Number two,
14 you're -- you're also targeting with what
15 you do the investors. That's critical for a
16 company at our stage.

17 You know, those would be -- you
18 know, those would be the two most important,
19 so --

20 Q. Anyone else?

21 A. Well, I mean, you're also -- I mean, you're
22 also -- you're also going to target general
23 pulmonologists. You're going to target all
24 of the physicians, you want to have an
25 awareness of that, and you want to target

1 future acquirers, you know, of the company,
2 you know, so, you know, you want to put out
3 to -- you want to reach out to all of them,
4 and you're happy to have patients gain
5 awareness of it as well.

6 Q. So, you won't reach out to patients?

7 A. Not directly, no.

8 Q. Okay. If you turn to the page Bate-numbered
9 538, there's a title there of the report
10 called Audience -- Audiences?

11 A. Which page?

12 Q. It's Bate-numbered 538.

13 A. I don't seem to have numbers on mine.

14 Q. It's on the right -- lower right. Yeah, you
15 got it right there.

16 A. Oh, here we go.

17 Q. Yep. So, it's titled, Audiences; you see
18 that at the top?

19 A. Um-hmm.

20 Q. And at the far right -- actually, let's back
21 up.

22 On the left, we have the medical
23 community, which you talked about, right,
24 the interventional pulmonologists,
25 et cetera; the financial community is to the

1 right of that medical community box; and
2 then at the far right, we have consumers?

3 A. Yes.

4 Q. So, you're -- you're telling me you're not
5 going to target consumers?

6 A. Our -- our marketing -- our marketing
7 efforts right now are clearly related to the
8 interventional pulmonologists. I mean, we
9 certainly don't want to hide this from the
10 patients. We do no active marketing to
11 patients, but eventually down the line --
12 down the line, if you have a novel medical
13 therapy, you wouldn't -- I mean, you're not
14 going to block that from happening, but
15 you're not going to spend money on it.

16 Q. You will not spend money on even down the
17 road on --

18 A. On actively reaching out to the patients. I
19 mean, this will be something with -- I mean,
20 patients with COPD and emphysema come to
21 their pulmonologist, and then -- and they --
22 it's that pulmonologist then that will be
23 the key decision-maker, the interventional
24 pulmonologist.

25 Q. So, will you make any -- once you're

1 commercialized, will you make any marketing
2 material that potentially could be
3 distributed to a consumer?

4 A. We have no plans at this point. Would we do
5 the stuff like what the pharmaceutical
6 companies do with direct TV marketing, I
7 actually don't believe in that.

8 Q. But you'll -- so, it's not in your plan to
9 create any marketing material, but is it a
10 possibility?

11 A. Maybe for some big company in the future.
12 They might choose to do it. It would be a
13 highly ineffective way to do it I think,
14 but --

15 Q. To market the Holaira?

16 A. To go direct to patients with a product that
17 only a highly sophisticated subspecialist --
18 I don't really see St. Jude and Medtronic
19 going to customers to market their
20 particular type of aortic valve prostheses,
21 you know, when they -- when the patient
22 would have no idea what the right prostheses
23 is for the aortic valve. It is possible?

24 Sure. It's not the primary target.

25 Q. But the Holaira device is tied closely to

1 TLD, correct?

2 MR. HANSEN: I'm just going to
3 lodge an objection. You're -- sometimes you
4 pronounce it Holaira, and sometimes you
5 pronounce it Olaira [ph]. I just want to
6 make sure that you're meaning Dr. Wahr's
7 company.

8 MR. WALZ: Well, as you know, I
9 mean, there's no right way to pronounce a
10 coined term. So --

11 MR. HANSEN: But I think the issue
12 is you're switching back and forth. I just
13 want to make sure that --

14 MR. WALZ: Yeah, Olaira, Holaira, I
15 mean, that's referring to -- yeah.

16 MR. HANSEN: Okay.

17 BY MR. WALZ:

18 Q. So, let's look at Exhibit Number 2, and if
19 we turn to the page Bate-numbered 111?

20 A. Got it.

21 Q. So, it's true that, at all times during this
22 naming and branding process, that your
23 company, you were aware of Boston
24 Scientific's Alair System, correct?

25 A. Yes.

1 Q. And this page that we're looking at, 111, is
2 the list of short names, as you testified
3 to, and you've also testified that you
4 needed to get creative people involved, you
5 needed to select a name -- a new name that
6 was completely unique, correct?

7 A. Yes.

8 Q. Unlike any other, correct?

9 A. That was the goal.

10 Q. Yet the Holaira mark that you ultimately,
11 you know, settled on has the L-A-I-R string
12 included in it, correct?

13 MR. HANSEN: Form.

14 THE WITNESS: Yes.

15 BY MR. WALZ:

16 Q. And that is the same string of letters
17 that's in the Boston Scientific Alair mark,
18 correct?

19 A. Yes.

20 Q. And you also testified that, based on
21 attending meetings, that you were aware of a
22 lot of "air" marks, although when you
23 referenced the piece of paper that you took
24 out of your pocket, there were only four
25 names on there, correct?

- 1 A. Four names on there, yep.
- 2 Q. And Xolair, you mentioned, was a drug?
- 3 A. Yes.
- 4 Q. Singulair is a pharmaceutical?
- 5 A. Yes.
- 6 Q. VitalAire is a pharmaceutical?
- 7 A. Yes.
- 8 Q. And Alere, L-A -- A-L-E-R-E, is that a
- 9 pharmaceutical as well?
- 10 A. Yes.
- 11 Q. Do you know how prevalent the use is of the
- 12 Xolair mark?
- 13 A. It's -- I don't. I don't know what their
- 14 market share is, no, but it's displayed
- 15 prominently at -- you know, on trade booths,
- 16 you know, at pulmonary meetings, so I assume
- 17 it's being used commercially quite a bit.
- 18 Q. Does the Holaira device compete with Xolair?
- 19 A. No.
- 20 Q. Does it compete with Singulair?
- 21 A. No.
- 22 Q. Does it compete with VitalAire?
- 23 A. No.
- 24 Q. And how about Alere?
- 25 A. No. It doesn't compete with bronchial

1 thermoplasty either.

2 Q. I didn't ask you that question, sir.

3 You also mentioned that you had
4 received from consumer feedback about the
5 Holaira mark in -- in connection with the
6 prefix "Ho," that you -- you had received
7 some -- some negative --

8 A. No.

9 Q. -- potential negative feedback?

10 A. No, we didn't -- that was an internal
11 concern when we just were talking about it,
12 you know, but no consumer feedback.

13 Q. So, you did no external testing or --

14 A. No.

15 Q. -- surveys or anything?

16 A. That was just our internal discussion.

17 Q. And when you testified that there had not
18 been any confusion, you had also testified
19 that you're not using the mark yet in the
20 United States, correct?

21 MR. HANSEN: Object to form,
22 foundation, misstates prior testimony.

23 MR. WALZ: You had asked him if he
24 had ever experienced -- or Holaira had
25 experienced any actual confusion, and he

1 said no.

2 MR. HANSEN: Yeah, and you added to
3 the question, and you said that, "you
4 haven't been using the mark in the
5 United States." I think he said it's on
6 their business cards, it's on their Website,
7 it's on their letterhead.

8 MR. WALZ: I take that back.

9 MR. HANSEN: I think you misstated
10 prior testimony.

11 BY MR. WALZ:

12 Q. Okay. So, you haven't used the Holaira mark
13 in connection with the system, the medical
14 device that you applied for, correct?

15 A. Applied for -- for to who? So, in the
16 United States, it's on our Website. We show
17 our business cards to US docs, you know, and
18 we -- and, you know, we aren't treating any
19 patients in the US, but, you know, US docs
20 clearly know about -- know about Holaira.

21 Q. It's on the device yet, correct?

22 A. Oh, you mean on a device that we use in a
23 clinical setting?

24 Q. Right.

25 A. But we -- well, first of all, we're not --

1 no, we haven't used the device in the US.

2 Q. Right.

3 A. But it's not on there anyway, but we haven't
4 used one even if it was.

5 Q. "Holaira" doesn't appear on the device?

6 A. I mean, not on our commercial device, no. I
7 mean, it's projected to be on our -- on our
8 device, you know, when we go commercial, but
9 right now we're just using a clinical
10 prototype.

11 Q. Yeah, I guess, just to clarify, when I'm
12 asking questions about sort of the use of
13 the Holaira mark, we both understand that
14 it's -- you're not commercialized yet, but
15 you're still in clinical.

16 So, when I'm talking about or
17 asking these questions, I'm asking -- I'm
18 referring to --

19 A. We anticipate to put "Holaira" -- the word
20 "Holaira" on the console.

21 Q. Right.

22 A. But it will say "dNerva" on the catheter.

23 Q. Okay.

24 MR. WALZ: Can we just take five
25 minutes, and I'll see if I've got anything

1 else, and we can wrap-up.

2 MR. HANSEN: Sounds like a plan.

3 MR. WALZ: Go enjoy our 4th of
4 July.

5 (Break taken.)

6 MR. WALZ: I've got no further
7 questions for you, Dr. Wahr.

8 MR. HANSEN: And I have no further
9 questions for you either, Dr. Wahr.

10 We'll read and sign. Thank you.

11 (At 11:40 a.m., the deposition was
12 recessed.)

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1	ERRATA SHEET		
2	Page/Ln	Correction	Reason
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1 I, DR. DENNIS WAHR, have read this
2 deposition transcript pages 1 - 112 and
3 acknowledge herein its accuracy except as
4 noted on the errata sheet.

5

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Signature

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Notary Public

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1 STATE OF MINNESOTA
CERTIFICATE

2 COUNTY OF WASHINGTON

3 I, Alexis Jensen, hereby certify
that I reported the deposition of
4 Dr. Dennis Wahr on the 2nd day of July, 2015
in Minneapolis, Minnesota, and that the
5 witness was by me first duly sworn to tell
the truth and nothing but the truth
6 concerning the matter in controversy
aforesaid;

7 That I was then and there a notary
8 public in and for the County of Washington,
9 State of Minnesota; that by virtue thereof I
 was duly authorized to administer an oath;

10 That the foregoing transcript is a
true and correct transcript of my
11 stenographic notes in said matter,
transcribed under my direction and control;

12 That the cost of the original has
13 been charged to the party who noticed the
14 deposition and that all parties who ordered
 copies have been charged at the same rate
 for such copies;

16 That the reading and signing of
the deposition was not waived;

17 That I am not related to any of
18 the parties hereto, nor interested in the
19 outcome of the action and have no contract
20 with any parties, attorneys or persons with
 an interest in the action that has a
 substantial tendency to affect my
 impartiality;

21 WITNESS MY HAND AND SEAL this 10th
day of July, 2015.

22
23

24 Alexis Jensen
Notary Public

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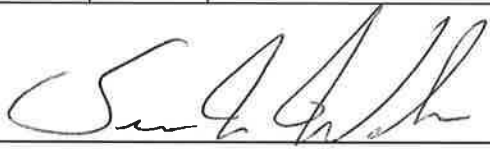
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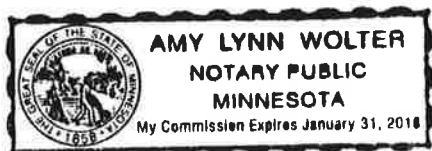
Errata Sheet for the Deposition of: **Dr. Dennis Wahr**, taken on 07/2/2015
Case Name: ***Boston Scientific and Ashmatx, Inc. v. Holaira, Inc.***

PAGE	LINE	FROM	TO	REASON FOR CHANGE
10	11	start	stop	Transcription Error
10	20	insert "it is my belief" before the word "all"		Correction
13	21	Interventional	Innovative	Misstatement
19	12	and	within	Correction
44	16	Alero	Alere	Transcription Error
44	20	Alero	Alere	Transcription Error
45	1	A-L-E-R-O	A-L-E-R-E	Misstatement
51	15-16	Delete "to understand your--your efficacy of a mark"	of your efficacy	Correction
54	15	Start	part	Transcription Error
92	5-6	it's not intended to avoid any of	it is intended to avoid the smooth	Transcription Error
93	13	an	on	Transcription Error
94	11	operable	off-label	Transcription Error
94	13	operable	off-label	Transcription Error


Witness Signature **Dennis Wahr**

7/28/15
Date


Notary Public



1 UNITED STATES PATENT AND TRADEMARK OFFICE
2 BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD
3 - - - - -
4 Boston Scientific Corporation and
5 Asthmatx, Inc.,
6 Opposers, Opposition No. 91215699
7 and
8 Holaira, Inc.,
9 Applicant.

10 - - - - -

11

12

13 - - - - -

14

15 DEPOSITION OF
16 DR. DENNIS WAHR

17

18 - - - - -

19

20

21

22

23

24 Taken July 2nd th, 2015 By Alexis Jensen

25

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22
23
24
25

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1 THE DEPOSITION OF DR. DENNIS WAHR,
2 is taken on this 2nd day of July, 2015, at
3 Oppenheimer, Wolff & Donnelly, LLP,
4 Campbell Mithun Tower, Suite 2000,
5 Minneapolis, Minnesota, commencing at
6 9:07 a.m.
7 DR. DENNIS WAHR,
8 having been called as a witness, being duly
9 sworn, testified as follows:
10 EXAMINATION
11 BY MR. HANSEN:
12 Q. Good morning, Dr. Wahr. I'd like to start
13 out today by just having a little bit of a
14 discussion about your background, okay?
15 A. Okay.
16 Q. Let's start with your education, starting
17 with college, and if you would, take me
18 through to your highest professional degree
19 or certification.
20 A. Okay. I went -- I went undergrad college to
21 a small liberal arts school in Michigan
22 called Albion College, A-L-B-I-O-N. Then I
23 went to medical school at Wayne State
24 University in Detroit, and then did my
25 internal medicine residency, three years, at

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1 I N D E X
2 Examination by Mr. Hansen, page 4
3 Examination by Mr. Walz, page 70
4
5 INDEX OF EXHIBITS
6
7 NUMBER DESCRIPTION
8
9 Exhibit 1 Holaira00615-67, page 23
10 Exhibit 2 Holaira000046-113, page 30
11 Exhibit 3 Holaira001388-93, page 70
12 Exhibit 4 TESS, Holaira, page 73
13 Exhibit 5 Trademark/Service Application,
14 dNerva, page 75
15 Exhibit 6 TESS, dNerva, page 76
16 Exhibit 7 COPD definition, page 83
17 Exhibit 8 Holaira000001-19, page 87
18 Exhibit 9 Holaira000486-96, page 97
19 Exhibit 10 (not marked)
20 Exhibit 11 Holaira000535-612, page 101
21
22 PREVIOUSLY-MARKED EXHIBITS REFERRED TO:
23 (NONE)
24
25

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1 the University of Michigan. Then I did my
2 cardiology fellowship at the University of
3 California, San Francisco, went to UCSF,
4 three years there, where I became an
5 interventional cardiologist.
6 I spent one year on faculty there
7 at UCSF. Then I went back to Michigan,
8 where I practiced cardiology for about
9 12 years at -- you know, in Ann Arbor, where
10 I was in private practice at St. Joseph
11 Mercy Hospital and was a clinical professor
12 of cardiology at the University of Michigan.
13 Then I took a leave of absence for
14 one year to come to Minneapolis and -- and
15 become a medical device entrepreneur. I
16 started my own medical device company, and
17 that was in the year 2001, and since -- and
18 never went back. I never went back and
19 practiced -- I took a one-year sabbatical
20 and never went back.
21 Q. When?
22 A. And have been here ever since, for the last
23 15 years.
24 Q. Were you a Board-certified interventional
25 cardiologist?

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1 A. Yes, yes, I was what they called triple
2 Board-certified. You know, I was
3 Board-certified in internal medicine. I was
4 Board-certified in cardiology and
5 Board-certified in interventional
6 cardiology; all three different levels of
7 Board certification.
8 Q. Okay. What's the -- what's the difference
9 between cardiology and interventional
10 cardiology?
11 A. Cardiologists do -- there's probably four
12 big divisions of cardiology. There's
13 interventional cardiology; there's
14 electrophysiology; there's diagnostic
15 cardiology, which would be things like
16 echocardiographies and MRI scans, you know,
17 they're almost like radiologists; and then
18 there's intensive care cardiology, you know,
19 working in ICUs and things like that.
20 And they all have their separate
21 Boards, so, you know, it just keeps getting
22 more and more subspecialized. So, a
23 cardiologist is kind of a generalist of
24 cardiology, and, you know, now there's these
25 four subspecialties of cardiology.

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1 Q. Okay.
2 A. It's pretty amazing. It's pretty
3 ridiculous.
4 Q. What -- what does an interventional
5 cardiologist do? Can you just describe
6 that?
7 A. Yeah, interventional cardiology is the part
8 of cardiology that does procedures on
9 patients, you know, and that's really the
10 first thing they started doing were
11 angioplasties. You know, in the mid '80s,
12 that really was origin of interventional
13 cardiology, fixing blocked arteries, working
14 through a pinhole.
15 That was the beginning of
16 interventional cardiology, the field of
17 interventional cardiology, but now it's
18 gradually expanded to where interventional
19 cardiologists do many different types of
20 procedures, all minimally -- from a
21 minimally-invasive approach. That's really
22 what defines it.
23 Q. When you were practicing as an
24 interventional cardiologist, did you use
25 medical devices?

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1 A. Absolutely, yeah.
2 Q. What -- what sorts of medical devices?
3 A. Well, certainly balloon angioplasty
4 catheters; stents, you know, the wire mesh
5 cylinders that we put in to scaffold open
6 blood vessels; atherectomy devices, which is
7 where you go in and carve out the plaque,
8 you know, and remove it; closure devices,
9 you know, where you go through pinholes to
10 close defects in the heart, you know, holes
11 between to atria and the ventricles, and
12 congenital abnormalities that are repaired
13 now through pinholes.
14 All of these things replaced the
15 need to have to have open-chest surgery.
16 And now, of course, the -- another big one
17 are the -- literally the percutaneous
18 valves. I mean, literally replacing valves
19 just through pinholes. I mean, those would
20 be the major areas of interventional
21 cardiology.
22 Q. Turning now to the entrepreneurial aspect of
23 your background.
24 In 2001, you mentioned that you
25 started --

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1 A. Yes.
2 Q. -- a medical device company.
3 What medical device company was
4 that?
5 A. It was called Velocimed, V-E-L-O-C-I-M-E-D.
6 Q. What types of product or products did --
7 A. We made --
8 Q. -- Velocimed make?
9 A. We made three different medical products.
10 One was what's called an -- and at the time
11 this was really the first one. It's
12 something called an embolic protection
13 device.
14 One of the risks of doing
15 angioplasty was sometimes you could go in,
16 inflate a balloon to dilate an artery, but
17 debris could break off and go downstream,
18 you know, and if that happened, you could
19 have damage downstream. Like if that would
20 break off and go to an important place, like
21 the brain or the kidney or something like
22 that, that was one of the areas of
23 complications.
24 So, we created a little basket that
25 could catch that that we'd put in first and

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1 then did the angioplasty, and if anything
2 went down, you would catch it.
3 Second product was something called
4 a PFO closure device, which was an
5 umbrella -- a little umbrella, miniature
6 umbrella, that you could put through a
7 pinhole and go in and close a hole between
8 the right and left atrium of the heart.
9 And the third one was what we
10 called a navigation catheter, because one of
11 the things that would start cardiologists
12 from being able to do a procedure is if they
13 couldn't get to that spot, you know, through
14 the curving blood vessels. So, we made a
15 catheter that could be, using a joystick,
16 directed to go around sharp curves.
17 St. Jude bought all three of those
18 products in the year -- I started the
19 company in 2001. St. Jude bought that
20 company in 2005, and all three products are
21 still -- are still being sold around the
22 world today. That was the first company.
23 Q. Were those products approved for sale by the
24 FDA?
25 A. All of them eventually achieved worldwide

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1 approval, including US.
2 Q. And what -- are you aware that the FDA
3 classifies medical devices in one of three
4 separate classes?
5 A. Yes.
6 Q. And what -- what class of device were the
7 three devices sold by or created by
8 Velocimed?
9 A. Well, the embolic protection device and the
10 PFO closure device were Class 3 devices.
11 The three classes are, you know, literally
12 1, 2, 3, where 3 is the -- the highest level
13 of sophistication, and, therefore -- you
14 know, or potential risk and the most novel,
15 which then means it needs the most testing.
16 Class 1 devices are typically
17 devices that are the least amount of risk,
18 and they're often -- they are often devices
19 that are copies of other devices that are
20 out there, that have predicates, and
21 everything's known about them, and it's just
22 kind of like one more copy doing the copycat
23 thing. You know, they can get a label as a
24 Class 1. Label 2 is somewhere in between.
25 The navigation device was Class 2.

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1 Q. Got it.
2 A. But then my second company Lutonix,
3 L-U-T-O-N-I-X, that was a Class 3 device
4 too.
5 Q. When did -- did you found Lutonix?
6 A. I founded both of these companies.
7 Q. And when -- when did Lutonix come into
8 being?
9 A. 2007, and CR Bard bought that company in
10 2000 -- in December of 2011.
11 Q. What product did Lutonix create?
12 A. We made an angioplasty balloon that had a
13 drug coating on it, and so, when you did
14 the -- so, when you would do the
15 angioplasty, the drug would transfer to the
16 blood vessel wall, and the drug would then
17 prevent the artery from re-narrowing, you
18 know, after you did the angioplasty.
19 Q. Is that angioplasty balloon approved by the
20 FDA?
21 A. Yes.
22 Q. And you mentioned that it was a Class 3
23 device?
24 A. 3, yep. First -- first drug-coated
25 angioplasty balloon in the world to be

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1 approved by the FDA. We got approval in
2 2012.
3 Q. Where are you currently employed Dr. Wahr?
4 A. Holaira, H-O-L-A-I-R-A.
5 Q. And when did you join that company?
6 A. I joined it in September of 2012.
7 Q. Did you found that company as well?
8 A. No.
9 Q. Who founded Holaira?
10 A. An individual called Marty Mayse, and
11 co-founded along with another person, an
12 engineer named Steve Dimmer. They were
13 co-founders.
14 Q. When you joined the company in 2012, was it
15 called Holaira?
16 A. No, the company was originally founded in
17 2008. That's when Marty Mayse and Steve
18 Dimmer founded the company. So, when I
19 joined the company, it was already four
20 years old, and the original name of the
21 company was InterventionalPulmonarySolutions
22 [sic], all one word. They -- they called it
23 IPS for short, to abbreviate it.
24 Q. Let's talk about the Holaira -- well,
25 actually, I should first ask you: What's

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1 your role at Holaira? What do you do there?

2 **A. I'm the CEO.**

3 Q. And have you always been the CEO?

4 **A. Yeah -- well, since they hired me, yeah, for**

5 **the last three years, yeah.**

6 Q. Okay. Let's talk about the -- the products

7 that Holaira creates.

8 What -- what is the product that

9 Holaira creates?

10 **A. We -- we have a product that's called -- the**

11 **name of the product is dNerva, and what it**

12 **is is it's a -- we use it to do a procedure**

13 **called targeted lung denervation, and the --**

14 **and the system that does it we call the**

15 **Holaira Lung Denervation System.**

16 Q. Can you describe for me what components

17 there are to the Holaira Lung Denervation

18 System?

19 **A. Yes, there are -- there's a -- the system**

20 **has a console. The console does really**

21 **three -- three things that are important.**

22 **It has a -- it's the generator for the**

23 **energy, you know, RF energy, radio frequency**

24 **energy, which is the power we use to -- for**

25 **the therapeutic effect, which I'll describe**

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1 in a minute.

2 It also has the pump in it, because

3 we have to circulate cold water, you know,

4 through the catheter while we do it. It

5 also has a -- so, therefore, it also has a

6 chilling -- a chiller in the console. And

7 then, of course, it has a user interface,

8 you know, which is a software program.

9 The console runs the dNerva

10 catheter, and the catheter is the active --

11 you know, is the therapeutic part of the

12 product, and the dNerva catheter is used by

13 an interventional pulmonologist. The

14 interventional pulmonologist takes the

15 dNerva catheter, and he puts it through the

16 working channel of a flexible bronchoscope,

17 you know, and flexible bronchoscopes are

18 something that interventional pulmonologists

19 have used for years.

20 It's still -- it's a flexible

21 catheter that goes down -- you know, in

22 through your mouth, down the trachea, and

23 they can look around inside the lungs with

24 this, but our catheter goes through the

25 working channel inside that bronchoscope,

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1 and when -- when the interventional

2 pulmonologist puts it down, he can position

3 it in both the right mainstem bronchus first

4 and then the left mainstem bronchus. You

5 can actually do it in either sequence.

6 That could be -- the working end of

7 the catheter has an electrode on it, which

8 is used to deliver the energy, and when that

9 electrode is positioned correctly inside the

10 right or left main bronchus, the energy can

11 be turned on, so that it delivers thermal

12 energy to the wall of the -- the main

13 right -- the right and left mainstem

14 bronchus that can denature the nerves that

15 go to the lung permanently, so that those

16 nerves are interrupted.

17 And what's great about that is

18 those nerves are what -- if you -- if you

19 interrupt those nerves, it allows the

20 airways to dilate, open.

21 Q. Let's just back up for a second.

22 You -- you referred to something

23 called a bronchus?

24 **A. Yes.**

25 Q. What is the bronchus?

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1 **A. Anatomically, your main airway. It comes**

2 **from your vocal cords. It's called the --**

3 **down to -- its first branch point is the**

4 **trachea, and that's the big airway. You can**

5 **feel it, you know, right -- right in your**

6 **throat.**

7 When that comes -- when that gets

8 down into the middle of the chest, it

9 branches into two main -- two large

10 branches, and those are call the right and

11 left mainstem bronchus, and then the

12 mainstem bronchus, in turn, branch into

13 multiple other airways, and then they keep

14 subdividing into -- and goes down into all

15 of the little billions of airways, you know,

16 out in the lungs.

17 Q. Okay. So, the -- the bronchus -- the

18 mainstem bronchus is outside of the lungs?

19 **A. Yes, you're not technically in the lungs**

20 **yet.**

21 Q. Okay. And then the bronchus stems out from

22 the mainstem bronchus and goes into the lung

23 fields?

24 **A. Yeah, it goes -- it goes -- basically, you**

25 **have the mainstem bronchus, and then you**

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1 **have secondary bronchi and then tertiary.**
2 **You know, it's just dividing and dividing**
3 **and dividing.**
4 Q. And describe for me, again, where the --
5 where within in the body the dNerva catheter
6 is used?
7 **A. In the right and left mainstem bronchus, in**
8 **just those first major divisions.**
9 Q. Okay.
10 **A. It never goes down into the lung fields.**
11 Q. And the -- what -- what condition is Holaira
12 seeking approval from the FDA to treat with
13 this device?
14 **A. Well, COPD, Chronic Obstructive Pulmonary**
15 **Disease, is the disease process, and in**
16 **patients that have COPD, COPD is**
17 **characterized by overactive nerves, you**
18 **know, that -- that are causing -- and these**
19 **overactive nerves cause the airways to be**
20 **constricted, you know, kind of in spasms, so**
21 **to speak, and up until this point in time,**
22 **the way COPD patients have been treated are**
23 **with inhalers.**
24 And, of course, you see this on
25 television all the time. Spiriva is the

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1 **leading selling pulmonary drug in the world,**
2 **maybe the first or second leading selling**
3 **drug of any kind in the world. You know,**
4 **the inhaler that you see people who can't**
5 **breathe puff on.**
6 And what that -- the way that
7 inhaler works, it goes down, and it
8 literally is trying to block the nerves, you
9 know, that go to the lungs so the airways
10 can open up. What we're trying to do, we're
11 going in, and we're -- by using this
12 RF energy and the right and left mainstem
13 bronchus, we're trying to ablate those
14 nerves, so that we -- so that we can
15 permanently -- get a permanent dilation, so
16 that you have a permanent bronchodilation.
17 So, it would become an alternative therapy
18 to drugs or even an additive, where we
19 actually know it would be an additive to
20 drugs, and there's a reason for that, to
21 benefit.
22 Q. Let's talk about the -- a little bit more
23 about the medical procedure in which the
24 Holaira Lung Denervation System is used.
25 You mentioned a name for the

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1 medical procedure itself. What was that
2 again?
3 **A. Targeted lung denervation.**
4 Q. Okay. And where is targeted lung
5 denervation performed? Like in what kind of
6 setting?
7 **A. It's in a hospital, a pulmonology procedure**
8 **room. It's in a special room that -- where**
9 **hospitals do these bronchoscopies**
10 **procedures.**
11 Q. What -- who performs the procedure?
12 **A. An interventional pulmonologist.**
13 Q. What's an interventional pulmonologist?
14 **A. Well, it goes -- it kind of goes back to the**
15 **same thing about when I talked about**
16 **interventional cardiologist.**
17 Until recently, until literally a
18 couple years ago, the -- the highest level
19 of certification within the field of
20 pulmonary was a Board-certified
21 pulmonologist, and these were doctors that
22 did bronchoscopies, you know, just that were
23 diagnostic, you would go and look around to
24 see what was in the lungs.
25 But in the last -- over the last

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1 number of few years, similar to what had
2 happened 15 or 20 years ago in cardiology, a
3 new field has arisen of interventional
4 pulmonology, where pulmonologists can do
5 additional training to become skilled at
6 actually doing invasive procedures, and this
7 group are what we refer to as the
8 interventional pulmonologists, and to be --
9 and that is a fully now recognized Board
10 certification-required subspecialty of
11 pulmonology, where they literally have to do
12 a two-year fellowship after training all the
13 previous stuff, do two additional years of
14 interventional pulmonology and then pass the
15 Boards to be a card-carrying credentialed
16 interventional pulmonologist, and they --
17 they do everything -- well, I shouldn't say
18 they do everything.
19 They do an awful lot. They do a
20 lot of different procedures now just through
21 the bronchoscope that used to require
22 open-chest surgery. You know, the same
23 story again like what happened 20 years ago
24 in cardiology, and they'll do everything
25 from putting in stents to dilating blocked

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1 airways to resecting tumors to, you know,
2 removing foreign bodies, just lots of
3 things.
4 So, we as a -- our procedure,
5 targeted lung denervation, is one of an
6 array of things that they do.
7 Q. You mentioned that -- how many of -- roughly
8 how many interventional pulmonologists are
9 there in the United States, if you know?
10 A. Today, there are about 150 roughly, about
11 150. So, you can kind of think of it as
12 each state -- if all states were average
13 size, there would be two or three in a
14 state.
15 It will grow. You know, the -- the
16 fellowship programs that train them are
17 turning out about, you know, seven or eight
18 new ones a year, you know, in the US, you
19 know, the specialized places that are
20 formally training them. So, that number
21 will -- I expect will slowly grow.
22 Q. Okay. Let's discuss a little bit how the
23 company changed names from IPS to Holaira,
24 and to assist with the -- the discussion,
25 I'll mark and hand you an exhibit.

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1 A. Sure.
2 (Exhibit Number 1 was marked.)
3 BY MR. HANSEN:
4 Q. Dr. Wahr, you've been handed what's been
5 marked as Wahr Exhibit 1.
6 Do you recognize this document?
7 A. Yes.
8 Q. What is it?
9 A. This is -- these are documents that we put
10 together not long after I took over as CEO
11 to help guide, you know, our renaming
12 process, you know, and also, you know, some
13 Board presentations that -- where we
14 actually conveyed some of this information
15 to our Board of Directors --
16 Q. Okay.
17 A. -- about why we were doing it.
18 Q. And was this a presentation present to the
19 Holaira Board of Directors?
20 A. Yes, this first one here, the open session
21 of the Board meeting. I mean, this was part
22 of the Board meeting where -- you know,
23 Board meetings have generally two parts.
24 They have what's called an open
25 session, where key company executives are

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1 included; and then there's what's called a
2 closed, where it's just me with the Board of
3 Directors period. You know, that's the part
4 where you talk about things like
5 compensation and confidential stuff that you
6 wouldn't want to have other people sitting
7 in on.
8 Q. During the --
9 A. Open session.
10 Q. -- open session, if you'd flip to page --
11 the twelfth slide in, which is -- has the
12 Bates number on the bottom right,
13 Holaira 627?
14 A. Yep.
15 Q. There is a -- appears to be a discussion
16 about branding activities?
17 A. Yep -- yes.
18 Q. What was the purpose of this -- the
19 inclusion of this slide in the presentation?
20 A. Well, I was -- I introduced it -- as you
21 noticed on the first page, the company was
22 still called Innovative Pulmonary Solutions
23 at this time, but I wanted to -- and I --
24 this -- this was really my first Board
25 meeting, you know, because I was hired in

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1 September, and this was December, and so,
2 this was my very first Board meeting that I
3 led, and I had already decided by that point
4 that I wanted to change the name of the
5 company, and this was my starting to
6 socialize that concept to the Board.
7 Now, you have to realize this was a
8 Board of Directors that had been with this
9 company for four years, you know, and so,
10 they were pretty -- you know, they were very
11 familiarized with the previous name, and so,
12 I just didn't want to come in and say I'm
13 changing, so how I'll commonly do things is
14 I'll introduce something and socialize it
15 and then -- then come back with a
16 recommendation at the next Board meeting.
17 It's a good way to run a company,
18 by the way, if you ever do this. Don't
19 blind-side your Board with just radical
20 stuff in the cold.
21 So, this was socializing the
22 concept that I was working my way towards
23 rebranding the company, which is a way of
24 saying, we're going to change the name,
25 we're going to change the Website. You

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1 know, we're going to -- you know, our
2 materials that are shown publicly, you know,
3 we're going to rethink.
4 Q. Why did you want to move away from the IPS
5 name?
6 A. Well, this was my third time around the
7 track, you know, with a company, and so,
8 while I don't consider myself a marketing
9 person, I'm used to working with marketing
10 people, and I do believe what they say.
11 And, to me, there were a couple --
12 there was a few problems with Innovative
13 Pulmonary Solutions.
14 Q. What were those problems?
15 A. Well, one is -- is that marketing people
16 will tell you that they really -- they would
17 never recommend the name of a company that
18 goes much more than two or three syllables.
19 Innovative Pulmonary Solution had 11. It's
20 too many words, you know, to be efficient,
21 you know.
22 And the second thing is is that it
23 was so long that you couldn't even fit it
24 into some URL boxes. You know, when you go
25 to type in your emails and stuff, it

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1 wouldn't fit, and, you know, you'd run out
2 of space, and then you were just stuck on a
3 lot of forms. I found that particularly
4 irritating.
5 The third thing was it was just
6 kind of a sentence. You know, it wasn't
7 really a unique word. Marketing people and
8 branding people want you to create your own
9 unique word. Because it wouldn't fit into
10 URL addresses, the company started calling
11 itself IPS for short, which is a
12 three-letter acronym, but the problem with
13 IPS was, one thing, marketing people don't
14 like acronyms, but, number two, it was
15 already trademark. I mean, in fact, it's
16 trademarked by about 15 people worldwide for
17 all kinds of different things. There's
18 absolutely nothing unique about IPS, you
19 know, as a three-letter thing -- thing out
20 there.
21 So -- so, for all of those reasons,
22 I felt we needed -- and since the company --
23 I had just become the new CEO, part of
24 becoming the new CEO was we were going to
25 move the company -- we decided we'd move the

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1 company from Seattle, where it had been the
2 first four years, to Minneapolis.
3 So, we were moving the company, and
4 it's going to be a new entity, you know,
5 here in Minneapolis, of which the people in
6 Minneapolis didn't even know -- you know,
7 there was no memory of the old name. So, it
8 was the perfect time to change the name.
9 Q. On the -- on slide 12, the third bullet
10 point down says: Need image that
11 demonstrates we are different from
12 competition, relevant to the target
13 audiences and credible.
14 Do you see that?
15 A. Yep.
16 Q. What was meant by "demonstrates we are
17 different from competition"?
18 A. This is a Class 3 device, first time -- and
19 it's very novel, first time anything like
20 this has ever been done in humans. You want
21 a name that is not confused with anything
22 else, you know, that is totally unique, that
23 will -- a new word -- a new word, you know,
24 created that will become the image of your
25 product, you know, that no physician will

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1 ever find confusing.
2 You know, that's fundamental --
3 that's what's fundamental. You don't -- you
4 know, when the Google people decided to have
5 a -- a search engine that you could find
6 anything on the Internet in 100th of a
7 second, they wanted a word that nobody had
8 seen before, and that's -- they created the
9 word "Google," which now everybody thinks
10 has been around for a century, when, in
11 fact, it's only been around for ten years,
12 because it was brand new. That's what
13 you're trying to do.
14 Q. After this Board meeting, did the -- did the
15 IPS continue in the process of rebranding?
16 A. Yes, the Board -- when I introduced this,
17 the Board gave me -- they said, yes, we're
18 interested in having this done, go do it.
19 Q. And what -- did Holaira, or IPS at the time,
20 retain any third-party entities to assist in
21 that process?
22 A. Yep, it's on here. You know, I had already
23 started the process, you know, with a
24 marketing consultant named Lorraine Wright
25 on the slide, and Lorraine, in turn, was

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1 working with a marketing company called
2 **Six Degrees.**
3 Q. Okay.
4 **A. Lorraine is not an employee of Six Degrees.**
5 **They are two different things. So, Lorraine**
6 **is our marketing person basically.**
7 MR. HANSEN: Let's mark that
8 exhibit.
9 (Exhibit Number 2 was marked.)
10 BY MR. HANSEN:
11 Q. Before we get into this next exhibit,
12 Dr. Wahr, you mentioned that Lorraine Wright
13 is not an employee?
14 **A. Right.**
15 Q. Although she's not an employee, is she
16 treated like -- as if she's an employee with
17 respect to her job function?
18 **A. Yes, she's our -- she's our only marketing**
19 **person we have. She does 100 percent of our**
20 **marketing activities, which, because we're**
21 **still a pre-revenue company, clinical stage,**
22 **as I call it, we don't really have a need**
23 **yet for a full-time marketing executive.**
24 So -- so, that's why she's still at
25 consultant status. I would estimate she

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1 probably spends about 50 percent of her time
2 working with us, but she has some other
3 clients, but she's our sole person, and she
4 carries a Holaira business card, has a
5 Holaira -- has a Holaira email address, and
6 she -- she is our -- she functions as if
7 she's a full-time employee. All
8 marketing-type questions, you know, that
9 flow through -- or inquiries from the
10 Website flow through her.
11 Q. Let's turn to Exhibit 2.
12 **A. Okay.**
13 Q. Have you seen Exhibit 2 before, Dr. Wahr?
14 **A. Yes.**
15 Q. What is Exhibit 2?
16 **A. These are the materials that were put**
17 **together by Six Degrees working with**
18 **Lorraine Wright that were literally the --**
19 **the documents we worked off of in our**
20 **company meetings as we started through a**
21 **methodical process of -- of considering**
22 **various alternatives for renaming the**
23 **company.**
24 Q. If you turn to the third slide in, which is
25 Bates number Holaira 48, there's a slide

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1 entitled: Naming Considerations?
2 **A. Yes.**
3 Q. The first bullet point says: The new name
4 must be shorter, simpler, fewer syllables.
5 What is that in reference to?
6 **A. That's in reference to our previous name of**
7 **Innovative Pulmonary Solutions that had 11**
8 **syllables.**
9 Q. Okay. If you turn to Holaira 50, which is
10 another couple of slides in, it's entitled:
11 Metrics for Naming?
12 **A. Yep.**
13 Q. Can you describe what the purpose of this
14 slide is?
15 **A. Yes, this is a -- this was a slide that**
16 **Six Degrees put together. I would say that**
17 **it's pretty much a boilerplate that**
18 **marketing firms use for how you -- you know,**
19 **it was not unique to us. It was unique to**
20 **what they do every time regardless of the**
21 **client, in terms of, when you start through,**
22 **how do you invent a new name or new word.**
23 By the way, this is kind of -- I
24 found this -- found this fascinating when I
25 got into this. There is no word in

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1 Webster's Dictionary that's not trademarked.
2 So, you can't name the company anything of a
3 word that exists. There -- whatever the
4 thousands of words, they're all trademarked.
5 So, the only way you can create a
6 new trademark is to come up with a brand new
7 word. Isn't that amazing? There are more
8 trademarks, in fact, than there are words in
9 the dictionary. So, you have to -- I
10 thought that was pretty -- pretty amazing,
11 you know, which is why you've got to get
12 creative people to do this stuff.
13 Now -- now, but these things here
14 are -- are what they say are -- are the
15 different categories of how you think about
16 it, you know, as you go about it as a team,
17 you know, association, different, clear,
18 pronounceable, memorable --
19 (Reporter clarification.)
20 THE WITNESS: The categories were
21 product association, different, clear,
22 pronounceable, memorable, positive and
23 available. All the categories that you
24 needed to -- you had to be able to have all
25 of these apply at the end of the day.

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1 BY MR. HANSEN:
2 Q. And we may have discussed this already, but
3 why was it important -- why was it an
4 important metric for the name to be
5 different from the competition?
6 A. Because we had -- we have a novel,
7 first-in-the-world-ever-done product. We
8 want -- we wanted no confusion that this had
9 any similarity to anything else. It had to
10 be totally unique, the word, to imply the
11 fact that this also was a totally unique
12 product.
13 Q. If you turn to the slide just before the one
14 that we're on, there's an identification of
15 a number of products that treat pulmonary
16 conditions, correct?
17 A. Yes.
18 Q. Why were you considering these other
19 entities and names in this process?
20 A. Because we knew that these were names of
21 products that interventional cardiologists
22 were already familiar with and using, and we
23 wanted to make sure that ours was -- you
24 know, was not similar to any of them. I
25 mean, again, getting back to the different

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1 and unique category.
2 Q. I think you said interventional
3 cardiologists --
4 A. Oh, did I say that?
5 Q. -- do you mean pulmonologists?
6 A. I continue to do that, because I used to be
7 one, but, yeah, interventional
8 pulmonologists. Glad Marty isn't here.
9 Q. If you turn to slide Holaira 56, it's
10 entitled: Naming Categories?
11 A. Yeah -- yes.
12 Q. Can you describe for me what -- what this
13 slide reflects and what these naming
14 categories mean?
15 A. Well, the way the marketing team helps
16 stimulate growth -- I mean, group-think is
17 to provide categories, you know, of
18 concepts, and they generally name, when
19 they -- you know, in doing this, they come
20 up with anatomic things or physiologic
21 things or structures, you know, that are --
22 that have something to do with what you're
23 doing, you know, and so, therefore, in terms
24 of what we do, it's -- it's pretty easy for
25 them to go nerve, air, pulmonary, lung,

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1 respiration, open -- you know, "open"
2 meaning open airway.
3 So -- and then they -- and then you
4 take each of those one by one and start to
5 create words that might be related or convey
6 or be related to these general categories.
7 Q. So, for example, air-centric?
8 A. Yes.
9 Q. What -- what impact does a word being
10 air-centric have on the word itself?
11 A. Well, I mean, each of these would -- would
12 commonly -- you know, would -- you work
13 around that. You start with that concept
14 of, say, air, and then you work around it
15 and try to mold words, you know, that might
16 encompass it.
17 Q. Okay. And why -- if you know, why were
18 these specific categories identified as
19 potential categories for words?
20 A. Because they related -- they all had
21 something to do with our procedure, you
22 know, what we do.
23 Q. If you turn -- we're going to jump around
24 just a little bit, but if you turn to the
25 third from last page of the slide deck,

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1 which is Holaira 111, there's a short list
2 of names.
3 Were there more names considered
4 than just this -- this short list?
5 A. Oh, yes, yeah, yeah. I mean, there were --
6 yeah, there were many, and in all of those
7 categories, there were a lot in each
8 category.
9 What these -- what these marketing
10 people do, they sit down and -- and they
11 provide you with a list to stimulate, you
12 know, all various renditions within these
13 categories.
14 Q. What -- what process was used to take the
15 longer list and winnow it down to the
16 shorter list?
17 A. We had -- we had a group meeting, where we
18 had -- there were really -- there were
19 really, you know, a smaller group of people,
20 four or five people, that -- that put the
21 most time into this.
22 It was myself; it was Marty Mayse;
23 it was Steve Dimmer, the other founder;
24 Lorraine Wright, we probably put in
25 relatively more time in discussion, but

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<p>1 there was also a larger group of some of the</p> <p>2 other employees in the company that were</p> <p>3 also brought in to comment on -- on just gut</p> <p>4 reaction, you know -- you know, what kinds</p> <p>5 of things that started to shake out as</p> <p>6 people's favorites.</p> <p>7 Q. Let's flip back in the slide deck to</p> <p>8 Holaira 65, which is an air-centric name,</p> <p>9 and the name is Holaira?</p> <p>10 A. Yep.</p> <p>11 Q. Ultimately, this is the name that the</p> <p>12 company selected, right?</p> <p>13 A. Yes.</p> <p>14 Q. Why did the company select the name Holaira?</p> <p>15 A. The -- there were -- there were several</p> <p>16 reasons that this one, as more and more</p> <p>17 discussion went, rose to the top, and the</p> <p>18 one that I liked the best was that the</p> <p>19 fundamental reason why I think our product</p> <p>20 is going to be so exciting in the</p> <p>21 marketplace is because the current standard</p> <p>22 of care for this disease is -- are these</p> <p>23 inhalers, these drugs, you know, that people</p> <p>24 breathe -- breathe in, but what's known</p> <p>25 by both -- all physicians know this, and the</p>	<p>1 going in and denervating the nerves in the</p> <p>2 right and left mainstem bronchus, and 100</p> <p>3 percent of all the nerves that go to the</p> <p>4 lungs go in -- are in the walls of that</p> <p>5 right and left mainstem bronchus. By</p> <p>6 denervating, we could dilate all the</p> <p>7 airways, the whole thing, the whole lung,</p> <p>8 and so, I love the concept that we'll be the</p> <p>9 first company that can truly deliver therapy</p> <p>10 to the whole lung, you know, and so -- and,</p> <p>11 whereas, I would say pharmaceuticals deliver</p> <p>12 therapy to only part of the lung. We're the</p> <p>13 whole lung.</p> <p>14 And so, the whole focus here was on</p> <p>15 whole, you know, W-H-O-L-E, but the</p> <p>16 marketing people, being the clever way they</p> <p>17 are, said, let's spell it H-O-L, because</p> <p>18 it's pronounced exactly the same way and</p> <p>19 it's clever. Now, you're looking like a</p> <p>20 unique word, as opposed to W-H-O-L-E, which</p> <p>21 is a word that everybody recognizes.</p> <p>22 So, shorten it to Hol, H-O-L. So</p> <p>23 air to the whole lung, and that really</p> <p>24 started to resonate to people as really a --</p> <p>25 a cool thing.</p>
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<p>1 pharmaceutical companies themselves</p> <p>2 acknowledge it, is that the Achilles heel of</p> <p>3 drugs that they don't talk about for</p> <p>4 treating lung disease is that, when they</p> <p>5 breathe these drugs in -- and they can only</p> <p>6 be given by -- by inhalation. They can't be</p> <p>7 given by swallowing pills, and there's</p> <p>8 reasons for that pharmacologically, but the</p> <p>9 drugs will go preferentially into those</p> <p>10 small airways that are wide open, and they</p> <p>11 won't go to the ones that are blocked, the</p> <p>12 drugs.</p> <p>13 So, the drugs, it's estimated,</p> <p>14 achieve only maybe at best 50 percent of the</p> <p>15 potential benefit that could be had if you</p> <p>16 had a way to get -- get -- you know, get, in</p> <p>17 effect, in all of the airways, not just the</p> <p>18 open ones, but that's also not really known</p> <p>19 for sure. People debate that.</p> <p>20 Some people say it's less even, you</p> <p>21 know, but -- so, drug therapy is really only</p> <p>22 treating part of the lung, you know, when</p> <p>23 these -- when it goes in, but it's still</p> <p>24 better than nothing.</p> <p>25 Our real benefit of our therapy by</p>	<p>1 The second thing was that -- was</p> <p>2 that, as the people started doing reviews,</p> <p>3 there's very, very few things in all of</p> <p>4 medicine, you know, whether it's drugs or</p> <p>5 procedures or -- or words or anything that</p> <p>6 begin with the letter H. H is really rare.</p> <p>7 So, it was extremely unique, and the other</p> <p>8 thing is is that we also found out the word</p> <p>9 holo, H-O-L-O, is actually another word that</p> <p>10 you can find out there, and actually its</p> <p>11 derivation is also whole, you know,</p> <p>12 actually. So, if you drop the W in -- you</p> <p>13 know, in languages, H-O-L-O, also means</p> <p>14 whole. So, it really came through that it</p> <p>15 was air to the whole lung and -- and really</p> <p>16 unique.</p> <p>17 The one thing that -- that I had a</p> <p>18 little hesitation about, which actually also</p> <p>19 makes it -- made it really unique, but was</p> <p>20 that we struggled with, and when we tested</p> <p>21 this around with different people, people</p> <p>22 had -- when they said, what do you think</p> <p>23 when you see this word? Well, you know,</p> <p>24 there's a derogatory street slang term</p> <p>25 called ho, you know, like that person's a</p>

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1 ho.
2 Anyway, but that is a negative
3 term, and -- and so, we struggled with the
4 fact that it would have too strong, you
5 know, a differential, you know, in terms of
6 a word being thrown into -- into medicine,
7 and so -- but the marketing people actually
8 kind of liked that, because it gave it more
9 of an edge, you know, of uniqueness. And,
10 by the way, nobody really thinks that, you
11 know, as our testing -- they really see
12 "whole," you know, is where they go.
13 Q. Can you describe for me how the company
14 pronounces its name?
15 A. Yeah, it's Hol, H-O-L, hyphen, second
16 syllable, is air, A-I-R, and the last
17 syllable is A. Three syllable, where it's
18 H-O-L, then second syllable A-I-R, another
19 syllable A, and we really differentiated --
20 we really wanted that differentiated all the
21 way to the point that on the -- that, on the
22 logo, we put an umbrella of dots over the
23 word A-I-R to differentiate the word "air"
24 and separate it from the syllable H-O-L, so
25 there was no -- no -- to really call that

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1 out, to get the word Hol on there, H-O-L,
2 and you've seen the -- it's on the business
3 cards. You've seen the logo.
4 Q. Going back to the -- the short list of -- of
5 names, there were -- at the back of the
6 slide deck, there are a number of names that
7 Holaira ultimately did not go with.
8 A. What page?
9 Q. 111?
10 A. Oh, 111.
11 Q. Yep. For example -- well, first, let me ask
12 you this: There are a number of names that
13 have Xs in the different columns.
14 A. Yeah.
15 Q. Would we take that to mean that the names
16 with Xs are in the running or out of the
17 running?
18 A. In the running.
19 Q. Why didn't Holaira end up using the name
20 Vitaira?
21 A. Well, you know, there were people that liked
22 Vitaira in the group, but -- but one of the
23 things that -- that became a differentiator
24 on that one was that, for whatever reason,
25 and these things tend to go in trends, but

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1 if you look at the last four or five years
2 of medical device company names, there have
3 been a lot of Vs. There's a lot of
4 companies out there that start with V, and
5 so, for that reason, that was a
6 discriminating -- that was probably one of
7 the main reasons why we moved away from that
8 at the end of the day. In discussion, in
9 fact, my first company had begun with a V,
10 Velocimed, and that was a bias to me. I
11 didn't want to do another V company.
12 Q. And why didn't you select Apaira?
13 A. Again, I think that it was a -- there are A
14 companies out there, and we thought that --
15 we thought that there was another company
16 out there called Alero, you know, that we
17 thought that looked a little close to, so we
18 thought Apaira was close to some other
19 competitors.
20 Q. And when you say "Alero," are you talking
21 about the product sold by Boston Scientific?
22 A. No.
23 Q. What --
24 A. It's a pharma -- it's a pharma drug.
25 Q. And how do you spell that?

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1 A. A-L-E-R-O, I think is the name of it -- is
2 how it's spelled.
3 Q. Ultimately, you went with one of the
4 air-centric names, Holaira?
5 A. Yes.
6 Q. Why did you go with an air-centric name?
7 A. It was a category people liked the best. I
8 mean, it is the fundamental basis of what we
9 do is to improve airflow to the lung. I
10 mean, it's -- it's the closest.
11 Q. Were you aware of any other company name,
12 product names or trademarks, that had the
13 word air within it when you made the
14 decision to go with an air-centric name?
15 A. Yes, there's a lot -- there's a lot of
16 "airs" out there.
17 Q. When you say "there's a lot of airs out
18 there," what do you mean?
19 A. I mean, there's a lot of companies -- I
20 mean, there's a lot of products out there
21 where the syllable A-I-R is a part of the
22 name.
23 Q. And what -- what field are those products?
24 MR. WALZ: Objection, foundation.
25 BY MR. HANSEN:

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1 Q. Do you know -- you mentioned that there's a
2 lot of words out there with "air" in it?
3 **A. Yes.**
4 MR. WALZ: Objection, foundation.
5 MR. HANSEN: To what?
6 MR. WALZ: How does he know that
7 there are a lot of products out there that
8 have "air" in it? You can lay the
9 foundation. I don't know how he knows that.
10 MR. HANSEN: He just testified that
11 he knows it.
12 MR. WALZ: How do you know it?
13 BY MR. HANSEN:
14 Q. Okay. Dr. --
15 **A. I've seen them a pulmonary meetings and**
16 **generally follow the literature.**
17 Q. Okay. So, you work at a company that has a
18 product -- is developing a product in the
19 pulmonary space, correct?
20 **A. Yes.**
21 Q. And through going to meetings in the
22 pulmonary space, you're aware of other
23 company names?
24 **A. And product names, yeah -- yes.**
25 Q. And is that how you're aware of other --

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1 can use it.
2 THE WITNESS: Okay.
3 BY MR. HANSEN:
4 Q. Dr. Wahr, what -- what examples are on that
5 piece of paper?
6 **A. Well, there's Singulair, Xolair, VitalAire**
7 **and Alere, A-L-E-R-E.**
8 Q. Turning back to my question about Alair, the
9 product sold by Boston Scientific, what
10 consideration, if any, did you take of the
11 existence of that name when deciding to use
12 the name Holaira?
13 **A. We wanted to make sure that we were very**
14 **different from any other word, and I would**
15 **say that that fell into that category. You**
16 **know, we were -- we -- as you saw in the**
17 **previous slide, we got the list of the other**
18 **leading -- or I shouldn't say leading, but**
19 **the known products that are used by**
20 **interventional pulmonologists, and so, we**
21 **looked at that entire list and said, are we**
22 **different than all of these words, you know,**
23 **and we were -- we were confident we were**
24 **different from all of these words, because**
25 **nobody had anything that looked like Hol,**

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1 **A. Yes.**
2 Q. -- names using the word "air"?
3 **A. Yes.**
4 Q. And are those other product names that are
5 in your mind in the pulmonary space?
6 **A. Yes.**
7 Q. Can you recall any of them?
8 **A. Xolair.**
9 Q. What does Xolair do?
10 **A. It's a drug.**
11 Q. What -- are you aware of the term "Alair"?
12 **A. Yes.**
13 Q. Sold by Boston Scientific?
14 **A. Yes.**
15 Q. Why -- what consideration, if any, did you
16 take of that name when deciding to choose
17 the name Holaira?
18 **A. Say that again.**
19 MR. WALZ: If I could, you took a
20 piece of paper out of your coat pocket, and
21 you now seem to be referring to it.
22 THE WITNESS: Yes, there's -- I
23 have four names of companies with "air" in
24 it that I think are really good examples.
25 MR. WALZ: Okay. That's fine. You

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1 **H-O-L, at the beginning of the word.**
2 Q. What -- why did you want to be different
3 from Alair?
4 **A. Because eventually -- because we have a**
5 **unique product, and we want our -- our**
6 **physicians, who are our main customers,**
7 **to -- to have no confusion about what we are**
8 **doing.**
9 Q. Let's turn to the -- the development of the
10 Holaira products.
11 I understand, and certainly tell me
12 if I'm wrong, I understand that the Holaira
13 product is not commercially available in the
14 United States?
15 **A. It's a clinical stage company.**
16 Q. When you say "it's a clinical stage
17 company," what do you mean?
18 **A. It's not approved for use, you know, for**
19 **commercial sale.**
20 Q. And what -- what process is the company
21 undertaking to become approved for
22 commercial sale?
23 **A. We're doing a -- we're working through**
24 **clinical trials, you know, human clinical**
25 **trials, and the -- the process that -- that**

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1 we're doing is we're doing a three --
2 three-stage development program, which has
3 began with Phase 1 clinical trials. We
4 finished that.

5 We're in what are now called
6 Phase 2 clinical trials, and then if our
7 data looks good in the Phase 2 trials, we'll
8 move on to what's called Phase 3 clinical
9 trials, which would be the pivotal trial.
10 We're in the middle of Phase 2 right now.

11 Q. Why is the company undertaking that process?

12 A. Well, the product is -- because the product
13 is novel and has never been done before, you
14 need to be very careful, you know, as you
15 work your way through the development
16 process, that you make sure that -- that
17 your product is safe, first of all, and the
18 way that's done in the eyes of the
19 regulatory authorities is they will approve
20 you to treat a small number of patients.

21 You treat those patients in the
22 Phase 1 trial, and then if that looks good,
23 then they'll give you a larger number of
24 patients you can treat, which is basically
25 Phase 2 trials. If that data looks good,

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1 everything has to be defined and done, and
2 then that's it, and that would be the trial
3 in which eventual approvals are based is
4 Phase 3.

5 Q. You mentioned earlier that there are three
6 classes of products within the FDA?

7 A. Right.

8 Q. What class of product is the Holaira System?

9 A. It's Class 3, and generally Class 3 products
10 are the products where you would go through
11 this type of extensive clinical testing
12 program.

13 Class 1 products, for example, may
14 not need any clinical testing at all. I
15 mean, they could literally just -- in
16 humans, they could just be developed on a
17 benchtop somewhere and get approval.

18 Generally, Class 2 products are
19 somewhere in between. Generally, they
20 require a -- some human testing in a trial,
21 but for sure Class 3 products require, you
22 know, an extensive development program since
23 it's never been done before, and you've
24 really got to prove that safety thing
25 before -- before they're going to let it go

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1 and basically Phase 1 and -- Phase 1 trials
2 are really focused on safety. You know,
3 they -- the way this works, they first want
4 to know that you're not going to hurt
5 anybody, and then if they -- if you pass
6 that bar, then you move on to where your
7 trials will be big enough that you can start
8 to, in followup testing, show that you're
9 actually beneficial, you know, but safety
10 comes first, and then you move on to the
11 benefit part.

12 So, Phase 2 kind of attempts to
13 re-corroborate the safety issue of Phase 1
14 in a large enough pool of patients that you
15 might be able to start to get a signal to
16 understand your -- your efficacy of a mark.
17 The other thing -- the other part about
18 Phase 2 trials is that you also are allowed
19 to start exploring some other parameters,
20 such as dose and, you know, some other
21 variables about your product.

22 Q. You mentioned --

23 A. But when you get to Phase 3 -- when you get
24 to Phase 3, you need to have your final
25 procedure and your energy dose and

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1 out on the market.

2 Q. What indication is being sought for the
3 Holaira products?

4 A. Patients of -- patients with moderate to
5 severe COPD.

6 Q. Let's turn now, Dr. Wahr, to the use of the
7 name Holaira.

8 When did -- when did the name
9 Holaira start being used by the company, if
10 you recall?

11 A. Probably in the first quarter, first quarter
12 of 2013. We -- yeah, plus or minus a month
13 or two, somewhere in there.

14 Q. And how is the -- how is the Holaira name --
15 how is the Holaira name used?

16 A. We use it -- I mean, it's the name of the
17 company. It's on the building. It's --
18 it's on our business cards. It's the name
19 on our Website, and it's -- and it's the
20 name on -- you know, on the product.

21 You know, I mean, it's the Holaira
22 Lung Denervation System. It's on the
23 console, and it's -- we use it on our slide
24 template -- our PowerPoint slide template
25 that we use when we present abstracts and

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1 our scientific data. I mean, it's the name
2 of -- it's the name of the system and the
3 name of the company, so it's on that stuff.
4 Q. At what events, if any, has Holaira
5 presented to physicians?
6 A. Publicly, public presentations of our
7 company to date has only happened one time,
8 and that was -- our coming-out party for
9 public presentation was at the European
10 Respiratory Society meeting in Munich,
11 Germany last fall.
12 That's the only public
13 presentation, you know, at a -- at a trade
14 show, and we did not have a booth. It
15 was -- we were start of the scientific
16 agenda. We had abstracts that were accepted
17 for presentation, and we did one evening
18 symposium, you know, where we summarized our
19 product for the -- you know, for the
20 attendees.
21 Q. And what were the attendees? Who was the
22 audience at that --
23 A. Primarily interventional pulmonologists, as
24 well as, in general, pulmonologists. That
25 would -- that made up the majority of the

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1 audience, and then there were industry
2 people there as well.
3 You know, whenever a new product is
4 kind of like shown at one of these meetings,
5 other companies that are in the space always
6 come out of interest as well, as you would
7 expect.
8 Q. When I asked a few questions ago, you made a
9 distinction, I think, between public and
10 private presentations?
11 A. Yes.
12 Q. Has the company done any private
13 presentations?
14 A. Yes. Oh, yes. I mean, everybody -- you
15 know, all of our physicians, who are
16 investigators in our clinical trials, you
17 know, obviously, have had private
18 presentations, and not only private
19 presentations, but have gone through
20 training, extensive training, on how to use
21 the device, and so, there's been meetings
22 with that group of doctors, but we also have
23 meetings with physicians in private that are
24 other key opinion leaders, KOLs, that stands
25 for key opinion leaders, leading physicians

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1 in the interventional pulmonary space, to
2 get their feedback and input and, you know,
3 reaction to what we're doing.
4 So there's been a number of those
5 meetings as well.
6 Q. And in those meetings you use the name
7 Holaira?
8 A. Yes.
9 Q. Approximately how many private presentations
10 would you say that Holaira has had?
11 A. Over -- since I have been CEO, those types
12 of meetings, fairly formal meetings, I would
13 say at least 50.
14 Q. And are those to interventional
15 pulmonologists in the United States or
16 elsewhere?
17 A. Both Europe and the United States.
18 Q. And within the United States, how many of
19 those types of meetings have you had?
20 A. Probably about a third of them have been
21 with US docs; two-thirds of them with
22 European physicians.
23 Q. Has --
24 A. Our US -- our US -- we have no US clinical
25 sites yet. You know, we're hopeful we'll

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1 have some later, you know, in the not too
2 distant future.
3 Q. Has Holaira used the name Holaira in any
4 press releases?
5 A. Yes.
6 Q. Do you know about how many in the last, what
7 is it, three and a half years?
8 A. Since I have been CEO, there have been five
9 press releases.
10 Q. What's the general topic of those press
11 releases, if you recall?
12 A. The majority of the -- most of them were
13 related to finance. It's common to do press
14 releases after you raise money successfully,
15 and -- or to announce, say, a key new
16 employee hire, and then I think one of them
17 was on -- you know, was announcing our
18 clinical data that was going to be shown at
19 the European Respiratory Society.
20 Q. Has Holaira --
21 A. They're -- they're all posted on the
22 Website.
23 Q. Has Holaira clinical data been published in
24 any medical journals?
25 A. Yes. Yeah, our Phase 1 -- our first

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1 **clinical trial now is published in a**
2 **peer-reviewed journal called Thorax.**
3 Q. Has -- are you aware of any confusion
4 between Holaira and Alair?
5 **A. None.**
6 Q. Are you aware of any confusion between or
7 about Holaira's affiliation or lack of
8 affiliation with Boston Scientific?
9 **A. None.**
10 Q. Let's turn now, Dr. Wahr, to the sales
11 process for the Holaira product.
12 First, who is the -- the target
13 customer for the Holaira products?
14 **A. The interventional pulmonologists.**
15 Q. Why is that?
16 **A. Because our product will -- will be labeled**
17 **that it is only for use by an interventional**
18 **pulmonologist. That will be -- and then**
19 **even if you are a Board-certified**
20 **pulmonologist, just that by itself is not**
21 **sufficient. You will also have to go**
22 **through and finish the formal training**
23 **program.**
24 Q. I'll dig into the formal training program in
25 just a minute.

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1 **A. Okay.**
2 Q. But you mentioned it will be labeled?
3 **A. Yeah.**
4 Q. What -- what does that mean, "it will be
5 labeled"?
6 **A. Well, the -- the -- when the FDA approves a**
7 **product, they -- they define in the label**
8 **who the patients are that -- what are the --**
9 **what are the inclusion criteria that the**
10 **patient must have in order to be a candidate**
11 **for the therapy.**
12 In our case, it would be moderate
13 to severe COPD, you know, and what the
14 testing parameters are that make that
15 patient formally eligible to get the
16 therapy; and, number two, what are -- what
17 are the requirements for a person to be --
18 to use the device.
19 You know, what is the training
20 qualifications, you know, for a person to be
21 able to use the device. Those are defined
22 as part of a product being approved by the
23 FDA.
24 Q. What -- what sales -- I understand the
25 product isn't commercially available as of

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1 yet, but does the company have some sense as
2 to what sales process it intends to employ
3 when the product becomes commercially
4 available?
5 **A. Yes. I mean, yes. I mean, we don't have a**
6 **detailed plan, because that's out there in**
7 **the future, you know, a number of years,**
8 **but -- but at a high level, yes, and our**
9 **plan for commercialization will be a direct**
10 **sales force.**
11 Q. And what do you know by a direct sales
12 force?
13 **A. Meaning --**
14 Q. Can you describe that?
15 **A. Meaning we will not use distributors or**
16 **other third-parties to -- to sell our**
17 **product.**
18 Q. And how would the -- what's the concept of
19 how the direct sales force would go about
20 selling the product?
21 **A. It would be -- it would be direct from -- I**
22 **mean, it would be direct to the**
23 **interventional pulmonologists. It would be**
24 **direct point-of-contact with the**
25 **interventional pulmonologists.**

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1 Q. You mentioned that that's a few years out.
2 Do you have an estimate as to how
3 far out that is?
4 **A. The -- the --**
5 Q. I should have asked a more clear question.
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 Q. You mentioned that training --
17 **A. Yes.**
18 Q. -- will be required to be able to use this
19 product?
20 **A. Yes.**
21 Q. What -- can you describe for me what that
22 training is?
23 **A. Yes, the -- the training program, it isn't**
24 **just a training program for a commercial**
25 **product. The training program is also a**

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1 requirement even to just be doing our
2 clinical trials at this point in time, you
3 know, where we -- anybody who's going to be
4 an investigator for us has to go through the
5 formalized training program, which consists
6 of both didactic, where it's slide
7 presentations, you know, to instruct them in
8 every aspect of how to use both the console
9 and the device itself, you know, how to run
10 them, how to position them.

11 But there's also a -- you know, so,
12 there's a mechanical part to it, but there's
13 also an education about patient selection,
14 you know, entry criteria, you know, for
15 patients and also how the patients are
16 followed up afterwards. So, it's a
17 comprehensive, you know, all -- all parts of
18 it.

19 And in addition to the didactic
20 presentations, there's also a hands-on
21 training process, where -- where they use
22 the device on a mannequin, as well as on a
23 human cadaver, in a cadaver lab.

24 Q. And who provides this training to
25 physicians?

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1 the whole clinical program, but I would
2 expect it will probably be in the
3 three-to-five-case range.

4 Q. How -- how, if at all, are patients targeted
5 for Holaira marketing?

6 A. We don't do any -- any -- any marketing to
7 patients, you know, at this point. Patients
8 have the potential to become aware of us,
9 you know, by finding -- you know, by
10 discovering it, you know, by reading
11 journals or going on the Website or things
12 like that, but we don't actively do any
13 marketing to patients.

14 Q. What is the -- does the company have a sense
15 as to what the price-point for the Holaira
16 System will be once it's commercially
17 available?

18 A. Well, it will be -- there's two components
19 to it. There would be the catheter, you
20 know, the dNerva catheter, will have --
21 which is a disposable, one-time use, and
22 will have one price; and then the console,
23 which can be used repeatedly, you know, on
24 many cases, will be another.

25 So, there will be two purchased

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1 A. The company. We do, the company. You know,
2 our -- our technical team.

3 Q. Company employees?

4 A. Company employees, yeah.

5 Q. Is there any support provided by company
6 employees at actual patient cases?

7 A. Yes. After -- after completing the training
8 program, there is company support at all of
9 the clinical cases, 100 percent of them, and
10 when -- and we anticipate that that will go
11 on throughout the entire clinical program,
12 and the term they use for this is
13 proctoring, you know, in the medical world;
14 and there will be a requirement that comes
15 in at the time of approval by the FDA for
16 when the product goes commercial will be a
17 specific designation for how many cases
18 after completing the training program a
19 physician has to be proctored before he can
20 really be turned loose, you know, to just do
21 these cases in an unsupervised fashion.

22 And where that number is going to
23 be for the number of required proctored
24 cases, isn't settled yet. I mean we'll
25 learn more about that as -- as we go through

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1 things; the console and the catheter. [REDACTED]

2 [REDACTED]
3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]

7 Q. Are you familiar -- in your time as an
8 interventional cardiologist, and as well as
9 based on your experience selling Class 3
10 medical devices, are you familiar with the
11 process for purchasing Class 3 medical
12 devices?

13 A. In hospitals?

14 Q. Correct.

15 A. Yes.

16 Q. What -- who makes the decision to purchase a
17 Class 3 medical device?

18 A. Hospitals have what's called a purchasing
19 department, and the purchasing department is
20 really the one that -- they issue the
21 checks. I mean, that's where -- that's the
22 key thing you got to get past, and they have
23 formalized processes for how they make the
24 decisions.

25 And, in general, the process starts

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1 when a physician tells the purchasing
2 department that there's a new product, or in
3 some cases, the product's been around, but
4 just hasn't been there on -- you know,
5 available before, a physician makes a
6 request that they would like to have a
7 product, you know, put in the inventory or
8 on the shelf, so to speak, at the hospital.
9 And then when that happens, a
10 process starts in the purchasing department,
11 where -- where it's basically an application
12 process where you have to educate the
13 purchasing department about what it is, what
14 its merits are, you know, what its potential
15 benefits are, you know, to the patient.
16 It's usually initiated by -- it can
17 be initiated by any one of the physician,
18 you know, specialties in the hospital.
19 Generally purchasing departments then
20 consider other things. They might -- they
21 might ask for feedback from other
22 specialties that would know about this.
23 They -- they would -- they may look for
24 medical society recommendations. They
25 would -- they also would look very carefully

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1 about whether there's reimbursement
2 available.
3 Sometimes hospitals will decide
4 this is a great product, but because no
5 reimbursement is available from the
6 insurance companies, they still won't put it
7 on the shelf. You know -- you know, and
8 that's when it sometimes comes into
9 conflict, you know, hospital -- I mean,
10 physicians versus hospitals that -- you
11 know, if the physicians want it, and the
12 hospital doesn't want to buy it, those are
13 interesting discussions, but it's a pretty
14 involved process.
15 Q. And why does the direct sales force -- or
16 why is the intent for the direct sales force
17 at Holaira to work directly with
18 interventional pulmonologists as opposed to
19 the purchasing department?
20 A. It's both a combination of the complexity of
21 the product, plus the cost, and -- and
22 that's too much to really rely on a
23 distributor for.
24 You know, distributors are
25 really -- in my experience, do best with

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1 commodity-type products, you know, that
2 don't require education. You know, like for
3 example, if you had a -- there's 30
4 different hip prostheses out on the market,
5 and they're very -- and in many cases very
6 hard to differentiate one from another. You
7 know, a company might give a distributor,
8 here's our hip prostheses, go out there and
9 sell it, and -- because it's not a technical
10 sale, and if -- but as products get more and
11 more sophisticated, it's a -- you need your
12 own highly, highly educated company
13 representative to go in there and -- and
14 educate -- you know, educate that physician,
15 and then the hospital too.
16 I mean, you know, the company reps
17 get involved in the -- in the education part
18 even working with the purchasing departments
19 as well.
20 Q. And what -- what role does the physician
21 have in the decision to purchase the
22 product?
23 A. He is a -- he makes a recommendation, but
24 his recommendation is essential to starting
25 the process. I don't know of any situation

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1 where a hospital purchasing department would
2 just, on their own, decide they want to put
3 something on the shelf. That wouldn't
4 happen.
5 Q. With a Class 3 medical device, is it
6 possible for a patient to purchase the
7 product?
8 A. No.
9 Q. Why not?
10 A. It can't be sold. It's not for sale to --
11 to patients. It's for sale only to -- to
12 the hospital's purchasing department on the
13 recommendation, you know, of the
14 pulmonologist.
15 Q. How would a patient who comes across the
16 Holaira name, once the product's
17 commercially available, how would that
18 patient possibly get the treatment?
19 A. They would have to -- they would have to
20 identify a hospital and physician that --
21 that are approved to do the procedure and go
22 to that medical center.
23 MR. HANSEN: Why don't we go off
24 the record. I'll go through my notes and
25 see if I have any other questions for you,

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1 Dr. Wahr.
2 THE WITNESS: Okay.
3 (Break taken.)
4 MR. HANSEN: Dr. Wahr, I have no
5 further questions for you at this time.
6 Thank you.
7 Do you want to take a break,
8 or do you want to --
9 MR. WALZ: Yeah, if we can take a
10 break, and I can just kind of get some docs
11 ready, and then we'll come back.
12 (Break taken.)
13 EXAMINATION
14 BY MR. WALZ:
15 Q. Dr. Wahr, are you ready?
16 A. Yes.
17 Q. Okay.
18 MR. WALZ: I'll just have you mark
19 this first.
20 (Exhibit Number 3 was marked.)
21 BY MR. WALZ:
22 Q. So, Dr. Wahr, you've been handed what's been
23 marked as Deposition Exhibit Number 3. This
24 was a document produced by Holaira.
25 Do you recognize that document?

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1 Q. Right. And you reviewed this application
2 before you signed it, correct?
3 A. Yes.
4 Q. And you understood what you were applying
5 for when you sign the application, correct?
6 A. Yes.
7 Q. And all the information in this application
8 was correct as of December 19th, 2012 when
9 the application was signed, correct?
10 A. I haven't -- it's been a long time since
11 I've read it, but I assume it was.
12 Q. So, if we look at the -- let's see here, if
13 we look at the page Bate-numbered 1391?
14 A. Yes.
15 Q. You will see, next to International Class
16 10, there's a description that reads:
17 Medical devices, medical apparatus and
18 instruments?
19 A. Yes.
20 Q. Now, that identification was at some point
21 amended; is that correct?
22 A. I don't know if we amended this or not. I
23 don't know the answer to that.
24 Q. Okay.
25 A. I don't understand your question.

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1 A. Yes.
2 Q. And if we turn to page -- well, it's
3 Bate-numbered 1392?
4 A. Yes.
5 Q. At the bottom there, there's -- next to
6 signature, Dennis W. Wahr; is that correct?
7 A. Yes.
8 Q. And that is your signature?
9 A. Yes.
10 Q. And --
11 A. Well, I don't see a signature, but it's my
12 name typed.
13 Q. That's an electronic signature, correct?
14 A. Oh, okay. All right.
15 Q. And you signed this application, correct?
16 A. I -- I probably did, yes. It's three years
17 ago.
18 Q. So, it's possible that someone else signed
19 this application?
20 A. No, I just don't see my signature on here.
21 MR. HANSEN: Objection to the form.
22 THE WITNESS: No. Yeah, so, you
23 know, I mean I'm taking your word for it
24 that somebody printed this up with numbers.
25 BY MR. WALZ:

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1 (Exhibit Number 4 was marked.)
2 BY MR. WALZ:
3 Q. So, you've been handed what's been marked as
4 Deposition Exhibit Number 4. This is a
5 printout from the United States Patent and
6 Trademark Office test database, and next to
7 the Goods and Services heading, there's a
8 description that reads: Medical devices for
9 treating obstructive lung diseases; medical
10 apparatus and instruments for treating
11 obstructive lung diseases.
12 Do you see that?
13 A. Yes.
14 Q. And that's different from the description we
15 saw on Exhibit 3, correct?
16 A. In that paragraph that starts,
17 "International Class;" you're referring to?
18 Q. Correct, on Exhibit Number 3.
19 A. Well, it's -- I mean, the wording is
20 slightly different, but it's saying the same
21 thing. I mean, it's -- it's a device for
22 treating obstructive -- it's a medical
23 apparatus and instrument. The one -- the
24 one on the right is -- looks like it's more
25 detailed.

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1 Q. And when you say "the right," you're
2 referring to Exhibit Number 4, correct?
3 **A. Right.**
4 Q. And looking at Exhibit Number 4, does that
5 description accurately reflect the device
6 that will be used in connection with the
7 Holaira mark?
8 **A. Yes, this is appropriate.**
9 Q. Okay. And you have no intention of further
10 amending or clarifying the identification
11 description that you see in Exhibit
12 Number 4, correct?
13 **A. Not at this point in time.**
14 Q. Okay. And just for a purpose of clarity, I
15 think when you were discussing before the
16 difference between dNerva -- the mark
17 dNerva --
18 **A. Yes.**
19 Q. -- and the Holaira mark, you mentioned that
20 dNerva will be used as the product name, but
21 that Holaira is going to be the company
22 name?
23 **A. Holaira -- Holaira is the company name. The**
24 **system, you know, the whole system that**
25 **consists of the console, you know, and the**

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1 **A. Yes.**
2 Q. And you did sign this application as well?
3 **A. Yes.**
4 Q. Okay. And then if we look on the third page
5 from the end, next to Class 10, we see
6 medical devices, medical apparatus and
7 instruments, correct?
8 **A. Yes.**
9 **(Exhibit Number 6 was marked.)**
10 BY MR. WALZ:
11 Q. So, you have been handed what's been marked
12 as Deposition Exhibit Number 6. This is a
13 printout from the United States Patent and
14 Trademark Office test database. It's for
15 the dNerva mark, and, again, next to the
16 heading Goods and Services, we see medical
17 devices for treating obstructive lung
18 diseases; medical apparatus and instruments
19 for treating obstructive lung diseases?
20 **A. Yes.**
21 MR. HANSEN: Objection, outside of
22 the scope of the direct examination.
23 BY MR. WALZ:
24 Q. And similar to the Holaira mark we saw
25 before, comparing the Exhibit 6 to

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1 **catheter, we call the Holaira Lung**
2 **Denervation System.**
3 Q. Okay.
4 **A. But the catheter, the catheter that's**
5 **disposable, the part that goes through the**
6 **bronchoscope, is the dNerva catheter.**
7 Q. I see, okay.
8 **(Exhibit number 5 was marked.)**
9 BY MR. WALZ:
10 Q. So, you have been handed what's been marked
11 as Deposition Exhibit Number 5.
12 Do you recognize this document?
13 **A. Yes.**
14 MR. HANSEN: I'll just object it's
15 outside the scope of the direct examination.
16 MR. WALZ: We'll bring it within
17 the scope.
18 THE WITNESS: Yes.
19 BY MR. WALZ:
20 Q. You do recognize it? Okay.
21 And if we flip to the second to the
22 last page again at the bottom, we see next
23 to signature, Dennis Wahr?
24 **A. Yes.**
25 Q. That is your signature?

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1 Exhibit 5, the description was amended,
2 correct, to what appears on Exhibit 6?
3 MR. HANSEN: Same objection.
4 You can answer.
5 THE WITNESS: Okay. The words on
6 the -- on the Exhibit 6 are -- are slightly
7 different than here, but, again, it appears
8 like they're saying the same thing.
9 BY MR. WALZ:
10 Q. And if we compare Exhibit 6 with, I
11 believe -- what was the Holaira -- I can't
12 remember the number -- test page? So, is
13 that Exhibit 4?
14 **A. 4.**
15 Q. So, if we compare what's in Exhibit -- the
16 identification in Exhibit 6 with the
17 identification of the goods description in
18 Exhibit 4, those descriptions are the same?
19 **A. They look the same.**
20 MR. HANSEN: Same objection.
21 BY MR. WALZ:
22 Q. Okay. And if you look at Exhibit 1 --
23 MR. HANSEN: Do you mean Exhibit 3,
24 Brad?
25 MR. WALZ: I'm sorry, Exhibit 3.

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1 BY MR. WALZ:
2 Q. If we look at the page that's numbered 1391,
3 underneath that International Class 10,
4 there's an Intent to Use, and it says: The
5 applicant has a bona fide intention to use
6 the -- or use through an applicant's related
7 company or licensee the mark in commerce or
8 in connection with the identified -- on or
9 in connection with the identified goods or
10 services.
11 Do you see that?
12 **A. Yes.**
13 Q. And at the time you signed this application,
14 you had the present intent to use the
15 Holaira mark in connection with a medical
16 device for treating obstructive lung
17 diseases, medical apparatus and instruments
18 for treating obstructive lung diseases,
19 correct?
20 **A. Yes, after going through all the appropriate**
21 **regulatory approvals.**
22 Q. Right.
23 **A. Yeah.**
24 Q. And after -- if we look at Exhibit 5, that's
25 the dNerva application, looking on page --

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1 page 4, under that International Class 10,
2 we have that same "intent to use" language?
3 MR. HANSEN: Object, outside the
4 scope.
5 You can answer.
6 THE WITNESS: Yes.
7 BY MR. WALZ:
8 Q. And the dNerva application was filed, if we
9 look at the second to the last page -- or
10 was signed, I should say, on April 25th,
11 2013, correct?
12 **A. Yes.**
13 Q. And then if we look at Exhibit 6, and we
14 look at the filing date, it was actually
15 filed the same day as well, correct?
16 **A. Yes.**
17 Q. And that's approximately four months after
18 the Holaira application, which is Exhibit 3,
19 was signed by you, correct?
20 **A. Yes.**
21 Q. So, my question is: How could you have a
22 bona fide intent to use the Holaira mark if
23 four months later you filed an application
24 for the dNerva mark with the exact
25 identification of goods descriptions?

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1 **A. Well, the -- we decided that we wanted a**
2 **distinct name for -- for the actual catheter**
3 **itself versus the system, and so, we wanted**
4 **one more -- we wanted a different -- it's**
5 **different parts of -- it's a specific part**
6 **of the bigger system.**
7 **You know, the system is the Holaira**
8 **Lung Denervation System, but the disposable**
9 **product is its own entity. It's different.**
10 Q. So, is the dNerva application, the ID in
11 that dNerva application, misdescriptive of
12 the goods that will actually be used in
13 connection with the mark?
14 MR. HANSEN: Object to form and
15 outside the scope.
16 BY MR. WALZ:
17 Q. I guess I'm trying to find out if one of
18 these applications is misdescriptive of --
19 of what you intend to use the mark for?
20 **A. Well, the -- the description is general. I**
21 **mean, they both apply. I mean, it's**
22 **accurate for both. It's a correct**
23 **designation for both -- both marks.**
24 Q. But you said dNerva would be used in
25 connection with the disposable catheter, not

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1 a medical device for treating obstructive
2 lung diseases?
3 **A. Well --**
4 MR. HANSEN: Object to the form.
5 THE WITNESS: Well, the catheter is
6 part of the system. So, it would be used in
7 the same way, and you're confusing me. I'm
8 not sure where you're going with that.
9 BY MR. WALZ:
10 Q. That's okay. We can move on.
11 **A. Okay.**
12 Q. So, the Holaira device can be used to treat
13 chronic asthma, correct?
14 **A. In theory, if we -- if we chose to go that**
15 **way, in theory, it could, yes. It would be**
16 **a completely new clinical development**
17 **program.**
18 Q. And that is an area that you're thinking of
19 expanding into, correct?
20 **A. Not right now.**
21 Q. But it is something that you have --
22 **A. It's theoretically possible that we could**
23 **make that decision at some point in the**
24 **future.**
25 Q. Right. But you've promoted that to

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1 potential investors and -- and identified it
2 as a potential area?
3 **A. Yes.**
4 Q. And you market -- as you testified, you
5 market the device to physicians, right,
6 interventional pulmonologists?
7 **A. Interventional pulmonologists.**
8 Q. Okay. And you're marketing that as a
9 treatment for COPD, correct?
10 **A. Correct.**
11 Q. And that term is understood as an umbrella
12 term, right?
13 **A. COPD, yes.**
14 Q. And so, under that umbrella, would include a
15 condition such as chronic asthma, correct?
16 **A. No. COPD is generally -- is generally felt**
17 **to have two major components. One would be**
18 **emphysema, and the other would be chronic**
19 **bronchitis.**
20 **Asthma is a -- is felt to be a**
21 **distinct different disease process. We --**
22 **we do not believe that -- we certainly**
23 **believe that asthma does not fall under our**
24 **label indications.**
25 MR. WALZ: Okay. Would you mark

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1 that as 7, I believe.
2 (Exhibit Number 7 was marked.)
3 BY MR. WALZ:
4 Q. So, you've been handed what's been marked as
5 Deposition Exhibit Number 7. It is a
6 printout from the
7 medical-dictionary.thefreedictionary.com.
8 These are definitions concerning COPD.
9 If you turn to page 5, and I guess
10 it flows over into page 6, and if you look
11 at page 6 first, this is -- well, the
12 definition that begins on page 5 for COPD
13 that turns over -- or spills over onto page
14 6 at the bottom, this is a definition from
15 McGraw-Hill Concise Dictionary of Modern
16 Medicine.
17 Do you see that at the bottom?
18 **A. Yes.**
19 MR. HANSEN: I'll object to the
20 document as containing hearsay.
21 BY MR. WALZ:
22 Q. So, if you turn to the first page -- or on
23 page 5, that final dictionary definition for
24 COPD states: Chronic Obstructive Pulmonary
25 Disease, Pulmonology, an umbrella term for a

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1 group of usually progressive lung disorders
2 with overlapping signs and symptoms,
3 including asthma.
4 Do you see that?
5 MR. HANSEN: Object, hearsay,
6 foundation.
7 THE WITNESS: I'm not sure what
8 page -- I can't seem to find the page you're
9 on.
10 BY MR. WALZ:
11 Q. So, at the top of each page, there are page
12 numbers; do you see that?
13 **A. Oh, okay. What page?**
14 Q. Page 5, and that definition begins at the
15 bottom and spills over.
16 So, I was saying, do you see on
17 page 5, that last definition of COPD?
18 **A. Yes.**
19 MR. HANSEN: Same objections.
20 BY MR. WALZ:
21 Q. And it says: Chronic Obstructive Pulmonary
22 Disease, Pulmonology, an umbrella term for a
23 group of usually progressive lung disorders
24 with overlapping signs and symptoms,
25 including asthma?

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1 MR. HANSEN: Same objection.
2 BY MR. WALZ:
3 Q. Do you see that?
4 **A. Yes.**
5 Q. Okay. And then if we turn to page 6, we see
6 another definition of COPD at the bottom.
7 This is from the Gale Encyclopedia of
8 Medicine, and it says: A term used to
9 describe chronic lung diseases, like chronic
10 bronchitis, emphysema and asthma?
11 MR. HANSEN: Same objections.
12 BY MR. WALZ:
13 Q. Do you see that?
14 **A. Yes.**
15 Q. Do you have any reason to dispute these
16 definitions?
17 **A. I think that our -- our definition of**
18 **Chronic Obstructive Pulmonary Disease is**
19 **what we -- our indications on our labelling**
20 **indication are for chronic bronchitis and**
21 **emphysema. Asthma is excluded. We don't**
22 **treat asthma.**
23 Q. Okay. But a doctor would understand, or a
24 physician would understand, the term "COPD"
25 according to these medical dictionary

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1 definitions to include asthma?

2 MR. HANSEN: Objection, form,

3 foundation and hearsay.

4 THE WITNESS: No, I don't agree.

5 BY MR. WALZ:

6 Q. But the Holaira System will compete with the

7 Alair System; is that correct?

8 **A. No, it will not.**

9 Q. You said though that the Holaira System

10 could possibly treat asthma?

11 **A. We have no clinical development program for**

12 **asthma, and every pulmonologist, as well as**

13 **interventional pulmonologist, sees them as**

14 **distinctly different diseases, and the only**

15 **way we could treat asthma would be if we**

16 **started over from scratch with a completely**

17 **new Phase 1, you know, feasibility study in**

18 **asthma patients, which, at this point, there**

19 **has been nothing initiated to start such a**

20 **program. It would be unaffordable for us to**

21 **do that.**

22 Q. To start --

23 **A. An asthma program.**

24 Q. -- an asthma program?

25 **A. Yes.**

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1 Q. But you are marketing that to your investors

2 as a potential area of growth, correct?

3 **A. If -- in the future, if a new -- if a new --**

4 **if another company were to buy Holaira, they**

5 **could make a decision to start an asthma**

6 **program in theory, but understand that it**

7 **would be going all the way back to the**

8 **starting point and starting at point 0 in**

9 **terms of that, and -- and the earliest**

10 **commercialization date for us to have a**

11 **label indication for asthma, if somebody**

12 **wanted to start that today, might be 2025.**

13 I mean, it's way out there, and it

14 would be another \$100 million development

15 program, which has not started at this

16 point.

17 **(Exhibit Number 8 was marked.)**

18 BY MR. WALZ:

19 Q. Showing you what's been marked as Deposition

20 Exhibit Number 8.

21 Do you recognize this document?

22 **A. Yes, yes.**

23 Q. And what is this?

24 **A. This is a presentation that I gave at the**

25 **Piper Jaffray Healthcare Conference.**

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1 Q. So, if you turn to page 2, in the heading,

2 it says: Holaira, Treatment For COPD and

3 Asthma, right?

4 **A. Yes, yes.**

5 Q. Okay. And if we look at page 11, it's

6 Bates-numbered 12 --

7 **A. Yes.**

8 Q. -- we see a -- a chart of revenue

9 projections, and then at the bottom of that

10 chart, there's a box?

11 **A. Yes.**

12 Q. And it says: COPD and asthma indication

13 split 70/30 in 2022?

14 **A. Yes.**

15 Q. And then if we turn to page 12,

16 Bates-numbered 13, and again we see at the

17 top in the heading, this is a competitive

18 landscape, and in the chart, there is, in

19 the second box below company product,

20 Holaira, and then if we go to the right

21 under COPD, there's a checkmark; under

22 asthma, there's a checkmark; and under

23 emphysema, there's a checkmark.

24 Do those checkmarks indicate that

25 the Holaira device can be used --

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1 **A. Yes.**

2 Q. -- to treat these conditions?

3 **A. Yes, it could, yes.**

4 Q. And then if we move below the Holaira box,

5 there's an entry for BSC that says, formerly

6 Astmatx/Alair; and under that, we see a

7 checkmark in asthma?

8 **A. Yes.**

9 Q. And that indicates that the Alair System is

10 used to treat asthma, correct?

11 **A. Yes.**

12 Q. And Boston Scientific is identified on a

13 chart where you've labeled it competitive

14 landscape as a competitor, correct?

15 **A. Yes.**

16 Q. And if we turn to the very last page -- I'm

17 sorry, page 17, Bates-labelled 18, we see a

18 slide labeled -- titled: Series D Financing

19 Highlights -- I'm sorry, are you there?

20 **A. Yeah, I know it. Go ahead.**

21 Q. And underneath the bullet point, Milestones

22 Through 2016, there's a subpoint for asthma

23 as part of the clinical heading?

24 **A. Yes.**

25 Q. And that there's six months of data from the

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1 asthma feasibility study.
2 Does this mean that you've already
3 started a feasibility study for the use --
4 use of the Holaira device to treat asthma?
5 **A. No, this was -- this was a slide done,**
6 **because at the time we were raising our**
7 **\$40 million, we did not have an asthma**
8 **program. We wanted to leave open the**
9 **possibility that if one of our investors --**
10 **if our lead investor wanted us to start one,**
11 **that's when this could be available, but, in**
12 **fact, when we closed the \$40 million**
13 **financing, our new investors did not want to**
14 **do an asthma program.**
15 **So, therefore, this has completely**
16 **dropped off the radar screen, if that makes**
17 **sense to you.**
18 Q. Yep.
19 **A. So, our clinical program is emphysema and**
20 **chronic bronchitis.**
21 Q. Let's talk a little bit about targeted lung
22 denervation.
23 So, I think, as you testified
24 before, targeted lung denervation, TLD, is
25 the generic name that you have created for

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1 your procedure, correct?
2 **A. Yes.**
3 Q. And that's similar to what, you know,
4 Boston Scientific had done with bronchial
5 thermoplasty?
6 **A. Exactly.**
7 Q. And TLD is a procedure that will require a
8 patient's informed consent, right?
9 **A. Yes.**
10 Q. And with respect to the informed consent
11 obligations, one of the things that will
12 have to be discussed is the nature of the
13 procedure, correct?
14 **A. Yes.**
15 Q. So, as you described before, the use of a
16 bronchoscope, the use of a catheter to place
17 a energy emitter within the main bronchi,
18 and then the administration of energy in
19 that main bronchi, correct?
20 **A. Correct.**
21 Q. And there will have to be a discussion with
22 the patient that the Holaira device will be
23 used as part of that TLD treatment?
24 **A. Absolutely.**
25 Q. And in discussing the nature of the

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1 procedure, you'll also have to explain to
2 the patient -- or the doctor will, I should
3 say, that, as you described, the treatment
4 is intended to denervate the nerves, that it
5 will not have -- it's not intended to avoid
6 any of the smooth muscle of the bronchi,
7 correct?
8 **A. Yes.**
9 Q. And, in fact, there is no effect to the
10 smooth muscle through targeted lung
11 denervation, correct?
12 **A. That -- that's what we believe, yeah.**
13 Q. So, then you will have to discuss the risk
14 and benefits with -- or the physician will,
15 with respect to TLD, and you'll also have to
16 discuss any alternatives, correct?
17 **A. Yes, yes.**
18 Q. And an alternative would be bronchial
19 thermoplasty?
20 **A. For what we do? No, bronchial thermoplasty**
21 **is not indicated for COPD -- I mean, for**
22 **chronic bronchitis or emphysema.**
23 Q. But that -- so, bronchial thermoplasty,
24 though, has an effect on the smooth muscle
25 tissue?

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1 **A. Yes.**
2 Q. And --
3 **A. That's what they say, yes.**
4 Q. And we talked about how COPD is an umbrella
5 term, and that chronic asthma is underneath
6 that umbrella?
7 **A. You -- you've completely manufactured that.**
8 **No interventional pulmonologist buckets**
9 **asthma with emphysema or chronic bronchitis.**
10 **Those are -- the two things that we treat**
11 **are completely different from asthma period.**
12 **That's why we have them in the three**
13 **columns. Boston cannot -- is not an label**
14 **to treat chronic bronchitis or emphysema.**
15 Q. But there are variations to asthma, isn't
16 there? You can have acute asthma?
17 **A. There -- there is a classification of**
18 **asthma, where -- where, in the severest**
19 **form, some of the pulmonologists will say**
20 **that it starts to look like COPD, but -- but**
21 **those are not -- those patients are not**
22 **included in our protocol or will be**
23 **on-label.**
24 Q. So, a patient --
25 **A. They're different.**

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1 Q. But a patient with chronic asthma, though,
2 if they were to talk to a physician about
3 TLD, a physician would have to have a
4 discussion at least about what treatment is
5 available for asthma, correct?
6 **A. No, because there's --**
7 MR. HANSEN: Object to form.
8 THE WITNESS: -- there's no label
9 indication for what we do.
10 BY MR. WALZ:
11 Q. Is there ever any operable use?
12 **A. Huh?**
13 Q. Does operable use happen at all?
14 **A. It never -- it never happens with a**
15 **non-commercially-approved product. [REDACTED]**
16 [REDACTED]
17 [REDACTED]
18 Q. Oh, right, obviously. We're not -- yeah,
19 right, I guess, yeah, to bring --
20 **A. I mean, if they want to go to jail, they can**
21 **do that if they want.**
22 Q. Yeah, we're talking about a product that is
23 not yet commercialized, right?
24 **A. Right.**
25 Q. We're talking about an intent to use

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1 trademark application.
2 So, just so I understand, as part
3 of a -- of a doctor's informed consent
4 obligation, you're saying that a patient
5 that they're advising with respect -- that
6 has chronic asthma would not have to be told
7 that, in addition to targeted lung
8 denervation, which could be used to treat
9 their condition, there's a separate
10 procedure called bronchial thermoplasty,
11 which could be an alternative to targeted
12 lung denervation?
13 MR. HANSEN: Object to the form,
14 lack of foundation.
15 THE WITNESS: Absolutely not.
16 You're really mixed up on this. You know,
17 the -- an asthma patient under any
18 circumstances, no doctor in the world would
19 tell an asthma -- would tell an asthma
20 patient that TLD is an alternative therapy
21 for what they have.
22 TLD at this point is an
23 experimental therapy only being tested in
24 chronic bronchitis and emphysema that, [REDACTED]
25 [REDACTED] they will get an approval, and

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1 there's nothing even in the works.
2 They would have absolutely no
3 obligation to tell a patient that.
4 BY MR. WALZ:
5 Q. Okay.
6 **A. And even if they did, it would be totally**
7 **unavailable.**
8 Q. Okay. So, what -- yeah, I guess, again,
9 we're talking -- again, you're not using the
10 mark -- the device -- so, I'm not talking
11 about -- we need to think about in terms of
12 when your product is actually available and
13 gets approval, [REDACTED]
14 **A. Right.**
15 Q. So, when you're both in the market --
16 **A. [REDACTED]**
17 Q. [REDACTED] So, the two treatments are now
18 actually available.
19 TLD is available to persons?
20 **A. For asthma -- I mean, excuse me, TLD for**
21 **chronic bronchitis and emphysema, right?**
22 Q. COPD, right?
23 **A. No.**
24 Q. That's --
25 **A. No, if you are choosing to arbitrarily use**

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1 **COPD as this higher bucket, like your thing**
2 **says, then -- then it's an inappropriate**
3 **umbrella, because we are only going to be**
4 **approved for emphysema and chronic**
5 **bronchitis.**
6 **(Exhibit Number 9 was marked.)**
7 BY MR. WALZ:
8 Q. Handing you what's been marked as Deposition
9 Exhibit 9.
10 If you turn to the second page?
11 **A. Yep.**
12 Q. This is -- it's titled: Six Degrees
13 Confidential Backgrounder.
14 Do you recognize this document?
15 **A. What's the date of this one? October 12.**
16 **Yeah, this one would have been created about**
17 **a week after I started, but I recognize a**
18 **lot of the things in here. I'm not sure**
19 **I've seen this before, but go ahead.**
20 Q. Okay. So, if we look at just even the
21 executive summary, and this was -- let me
22 back up.
23 I mean, the intent of this document
24 was to educate Six Degrees, who was your
25 marketing firm that was retained to help you

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1 with the naming process, right --
2 **A. Yes.**
3 Q. -- to understand your company?
4 **A. Yes.**
5 Q. Okay. So, in the executive summary, there,
6 it says that: IPS is a system -- the main
7 objective of the IPS System is the
8 development of a commercial product to
9 enable a new therapeutic procedure, TLD,
10 which will improve respiratory function for
11 moderate to severe COPD patients?
12 **A. Yes.**
13 Q. And it doesn't say chronic bronchitis or
14 emphysema, correct?
15 **A. You know --**
16 MR. HANSEN: Feel free to review
17 the entire document before you answer
18 questions about it.
19 THE WITNESS: Yeah, I think you're
20 taking this out of context. Our COPD
21 definition that we use throughout the entire
22 company is COPD is chronic bronchitis and
23 emphysema. It is not asthma. Our clinical
24 programs, you know, make it clear that
25 asthma is not included.

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1 But, by the way, could our device
2 eventually at some point be used to treat
3 asthma? The answer is yes, and I've said
4 that already, but we're not developing it
5 for that. So, that's the answer to your
6 question.
7 You know, so --
8 BY MR. WALZ:
9 Q. Okay.
10 **A. -- I mean, you're arguing over the semantics**
11 **of this, but I can promise you, in**
12 **interventional pulmonology, we can bring in**
13 **20 experts, and they all see asthma,**
14 **chronic bronchitis and emphysema as three**
15 **completely different entities.**
16 Now, most people traditionally
17 would put just two of them under COPD,
18 chronic bronchitis and -- chronic bronchitis
19 and emphysema under COPD. That's what you
20 see under every commercial on TV when you
21 see Spiriva advertised. And they put asthma
22 over here in a different category, because
23 its mechanism of action is different, and
24 it's a different disease process.
25 Q. Right.

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1 **A. And -- and that's -- that's how we use it,**
2 **but the point is is that I'm not denying the**
3 **fact that, if we ever -- if a future owner**
4 **or investor or something wanted to start an**
5 **asthma program, our device could -- could do**
6 **that, and that's why it appears in there.**
7 I'm just simply saying we're not doing that
8 right now.
9 Q. Right.
10 **A. And -- and if somebody decided to do it, it**
11 **would be way out there.**
12 Q. Okay.
13 **A. And I don't understand what that has to do**
14 **with the trademark anyway.**
15 Q. Yeah, this is just -- this is just -- you
16 know, in all of the documents I've seen
17 produced by Holaira --
18 **A. Yeah.**
19 Q. -- reference is always made to COPD. So,
20 that's why I just wanted to get some
21 clarification as, you know -- and you even
22 describe it on your Website as an umbrella
23 term?
24 **A. Over --**
25 Q. So --

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1 **A. -- over CO -- over emphysema and chronic**
2 **bronchitis, yes.**
3 Q. But as we saw in some of those medical
4 definitions, you know, asthma has been
5 included as -- under the umbrella?
6 **A. I will go on the record though as the vast**
7 **majority of people in this space of the**
8 **experts separate asthma under a completely**
9 **separate umbrella and not under the COPD**
10 **umbrella. That's my statement, but it**
11 **doesn't matter to this anyways.**
12 Q. That's your opinion, right?
13 **A. Right, it's my opinion, and it's clearly**
14 **the -- the opinion of the vast majority of**
15 **people that this is how they would classify**
16 **it.**
17 (Exhibit Number 11 was marked.)
18 BY MR. WALZ:
19 Q. So, you have been handed what's been marked
20 as Exhibit 11. This is an email from
21 Mark Laverman to Lorraine and also yourself.
22 You are identified as a recipient, and this
23 email attached two PowerPoint presentations.
24 One is the messaging blueprint, and
25 the second is the -- the naming -- what is

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1 it called? Is it the naming concept?

2 So, you previously testified that

3 you were targeting only interventional

4 pulmonologists with respect to your sales

5 efforts?

6 **A. It was the primary target.**

7 Q. So, it's not the only target?

8 **A. It's not the only target.**

9 Q. Okay. What are some of the other targets?

10 **A. Well, if you're putting -- if you wear my**

11 **hat as the CEO, my primary targets are,**

12 **number one, the customer, which is**

13 **interventional pulmonologists. Number two,**

14 **you're -- you're also targeting with what**

15 **you do the investors. That's critical for a**

16 **company at our stage.**

17 You know, those would be -- you

18 **know, those would be the two most important,**

19 **so --**

20 Q. Anyone else?

21 **A. Well, I mean, you're also -- I mean, you're**

22 **also -- you're also going to target general**

23 **pulmonologists. You're going to target all**

24 **of the physicians, you want to have an**

25 **awareness of that, and you want to target**

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1 **future acquirers, you know, of the company,**

2 **you know, so, you know, you want to put out**

3 **to -- you want to reach out to all of them,**

4 **and you're happy to have patients gain**

5 **awareness of it as well.**

6 Q. So, you won't reach out to patients?

7 **A. Not directly, no.**

8 Q. Okay. If you turn to the page Bate-numbered

9 538, there's a title there of the report

10 called Audience -- Audiences?

11 **A. Which page?**

12 Q. It's Bate-numbered 538.

13 **A. I don't seem to have numbers on mine.**

14 Q. It's on the right -- lower right. Yeah, you

15 got it right there.

16 **A. Oh, here we go.**

17 Q. Yep. So, it's titled, Audiences; you see

18 that at the top?

19 **A. Um-hmm.**

20 Q. And at the far right -- actually, let's back

21 up.

22 On the left, we have the medical

23 community, which you talked about, right,

24 the interventional pulmonologists,

25 et cetera; the financial community is to the

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1 right of that medical community box; and

2 then at the far right, we have consumers?

3 **A. Yes.**

4 Q. So, you're -- you're telling me you're not

5 going to target consumers?

6 **A. Our -- our marketing -- our marketing**

7 **efforts right now are clearly related to the**

8 **interventional pulmonologists. I mean, we**

9 **certainly don't want to hide this from the**

10 **patients. We do no active marketing to**

11 **patients, but eventually down the line --**

12 **down the line, if you have a novel medical**

13 **therapy, you wouldn't -- I mean, you're not**

14 **going to block that from happening, but**

15 **you're not going to spend money on it.**

16 Q. You will not spend money on even down the

17 road on --

18 **A. On actively reaching out to the patients. I**

19 **mean, this will be something with -- I mean,**

20 **patients with COPD and emphysema come to**

21 **their pulmonologist, and then -- and they --**

22 **it's that pulmonologist then that will be**

23 **the key decision-maker, the interventional**

24 **pulmonologist.**

25 Q. So, will you make any -- once you're

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1 commercialized, will you make any marketing

2 material that potentially could be

3 distributed to a consumer?

4 **A. We have no plans at this point. Would we do**

5 **the stuff like what the pharmaceutical**

6 **companies do with direct TV marketing, I**

7 **actually don't believe in that.**

8 Q. But you'll -- so, it's not in your plan to

9 create any marketing material, but is it a

10 possibility?

11 **A. Maybe for some big company in the future.**

12 **They might choose to do it. It would be a**

13 **highly ineffective way to do it I think,**

14 **but --**

15 Q. To market the Holaira?

16 **A. To go direct to patients with a product that**

17 **only a highly sophisticated subspecialist --**

18 **I don't really see St. Jude and Medtronic**

19 **going to customers to market their**

20 **particular type of aortic valve prostheses,**

21 **you know, when they -- when the patient**

22 **would have no idea what the right prostheses**

23 **is for the aortic valve. It is possible?**

24 **Sure. It's not the primary target.**

25 Q. But the Holaira device is tied closely to

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1 TLD, correct?

2 MR. HANSEN: I'm just going to

3 lodge an objection. You're -- sometimes you

4 pronounce it Holaira, and sometimes you

5 pronounce it Olaira [ph]. I just want to

6 make sure that you're meaning Dr. Wahr's

7 company.

8 MR. WALZ: Well, as you know, I

9 mean, there's no right way to pronounce a

10 coined term. So --

11 MR. HANSEN: But I think the issue

12 is you're switching back and forth. I just

13 want to make sure that --

14 MR. WALZ: Yeah, Olaira, Holaira, I

15 mean, that's referring to -- yeah.

16 MR. HANSEN: Okay.

17 BY MR. WALZ:

18 Q. So, let's look at Exhibit Number 2, and if

19 we turn to the page Bate-numbered 111?

20 **A. Got it.**

21 Q. So, it's true that, at all times during this

22 naming and branding process, that your

23 company, you were aware of Boston

24 Scientific's Alair System, correct?

25 **A. Yes.**

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1 Q. And this page that we're looking at, 111, is

2 the list of short names, as you testified

3 to, and you've also testified that you

4 needed to get creative people involved, you

5 needed to select a name -- a new name that

6 was completely unique, correct?

7 **A. Yes.**

8 Q. Unlike any other, correct?

9 **A. That was the goal.**

10 Q. Yet the Holaira mark that you ultimately,

11 you know, settled on has the L-A-I-R string

12 included in it, correct?

13 MR. HANSEN: Form.

14 THE WITNESS: Yes.

15 BY MR. WALZ:

16 Q. And that is the same string of letters

17 that's in the Boston Scientific Alair mark,

18 correct?

19 **A. Yes.**

20 Q. And you also testified that, based on

21 attending meetings, that you were aware of a

22 lot of "air" marks, although when you

23 referenced the piece of paper that you took

24 out of your pocket, there were only four

25 names on there, correct?

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1 **A. Four names on there, yep.**

2 Q. And Xolair, you mentioned, was a drug?

3 **A. Yes.**

4 Q. Singulair is a pharmaceutical?

5 **A. Yes.**

6 Q. VitalAire is a pharmaceutical?

7 **A. Yes.**

8 Q. And Alere, L-A -- A-L-E-R-E, is that a

9 pharmaceutical as well?

10 **A. Yes.**

11 Q. Do you know how prevalent the use is of the

12 Xolair mark?

13 **A. It's -- I don't. I don't know what their**

14 **market share is, no, but it's displayed**

15 **prominently at -- you know, on trade booths,**

16 **you know, at pulmonary meetings, so I assume**

17 **it's being used commercially quite a bit.**

18 Q. Does the Holaira device compete with Xolair?

19 **A. No.**

20 Q. Does it compete with Singulair?

21 **A. No.**

22 Q. Does it compete with VitalAire?

23 **A. No.**

24 Q. And how about Alere?

25 **A. No. It doesn't compete with bronchial**

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1 **thermoplasty either.**

2 Q. I didn't ask you that question, sir.

3 You also mentioned that you had

4 received from consumer feedback about the

5 Holaira mark in -- in connection with the

6 prefix "Ho," that you -- you had received

7 some -- some negative --

8 **A. No.**

9 Q. -- potential negative feedback?

10 **A. No, we didn't -- that was an internal**

11 **concern when we just were talking about it,**

12 **you know, but no consumer feedback.**

13 Q. So, you did no external testing or --

14 **A. No.**

15 Q. -- surveys or anything?

16 **A. That was just our internal discussion.**

17 Q. And when you testified that there had not

18 been any confusion, you had also testified

19 that you're not using the mark yet in the

20 United States, correct?

21 MR. HANSEN: Object to form,

22 foundation, misstates prior testimony.

23 MR. WALZ: You had asked him if he

24 had ever experienced -- or Holaira had

25 experienced any actual confusion, and he

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1 said no.

2 MR. HANSEN: Yeah, and you added to

3 the question, and you said that, "you

4 haven't been using the mark in the

5 United States." I think he said it's on

6 their business cards, it's on their Website,

7 it's on their letterhead.

8 MR. WALZ: I take that back.

9 MR. HANSEN: I think you misstated

10 prior testimony.

11 BY MR. WALZ:

12 Q. Okay. So, you haven't used the Holaira mark

13 in connection with the system, the medical

14 device that you applied for, correct?

15 **A. Applied for -- for to who? So, in the**

16 **United States, it's on our Website. We show**

17 **our business cards to US docs, you know, and**

18 **we -- and, you know, we aren't treating any**

19 **patients in the US, but, you know, US docs**

20 **clearly know about -- know about Holaira.**

21 Q. It's on the device yet, correct?

22 **A. Oh, you mean on a device that we use in a**

23 **clinical setting?**

24 Q. Right.

25 **A. But we -- well, first of all, we're not --**

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1 else, and we can wrap-up.

2 MR. HANSEN: Sounds like a plan.

3 MR. WALZ: Go enjoy our 4th of

4 July.

5 (Break taken.)

6 MR. WALZ: I've got no further

7 questions for you, Dr. Wahr.

8 MR. HANSEN: And I have no further

9 questions for you either, Dr. Wahr.

10 We'll read and sign. Thank you.

11 (At 11:40 a.m., the deposition was

12 recessed.)

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1 **no, we haven't used the device in the US.**

2 Q. Right.

3 **A. But it's not on there anyway, but we haven't**

4 **used one even if it was.**

5 Q. "Holaira" doesn't appear on the device?

6 **A. I mean, not on our commercial device, no. I**

7 **mean, it's projected to be on our -- on our**

8 **device, you know, when we go commercial, but**

9 **right now we're just using a clinical**

10 **prototype.**

11 Q. Yeah, I guess, just to clarify, when I'm

12 asking questions about sort of the use of

13 the Holaira mark, we both understand that

14 it's -- you're not commercialized yet, but

15 you're still in clinical.

16 So, when I'm talking about or

17 asking these questions, I'm asking -- I'm

18 referring to --

19 **A. We anticipate to put "Holaira" -- the word**

20 **"Holaira" on the console.**

21 Q. Right.

22 **A. But it will say "dNerva" on the catheter.**

23 Q. Okay.

24 MR. WALZ: Can we just take five

25 minutes, and I'll see if I've got anything

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1 ERRATA SHEET

2 Page/Ln Correction Reason

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1 I, DR. DENNIS WAHR, have read this
2 deposition transcript pages 1 - 112 and
3 acknowledge herein its accuracy except as
4 noted on the errata sheet.
5
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7

8 -----
9 Signature

10 -----
11 Notary Public
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1 STATE OF MINNESOTA
2 CERTIFICATE

3 COUNTY OF WASHINGTON

4 I, Alexis Jensen, hereby certify
5 that I reported the deposition of
6 Dr. Dennis Wahr on the 2nd day of July, 2015
7 in Minneapolis, Minnesota, and that the
8 witness was by me first duly sworn to tell
9 the truth and nothing but the truth
10 concerning the matter in controversy
11 aforesaid;

12 That I was then and there a notary
13 public in and for the County of Washington,
14 State of Minnesota; that by virtue thereof I
15 was duly authorized to administer an oath;

16 That the foregoing transcript is a
17 true and correct transcript of my
18 stenographic notes in said matter,
19 transcribed under my direction and control;

20 That the cost of the original has
21 been charged to the party who noticed the
22 deposition and that all parties who ordered
23 copies have been charged at the same rate
24 for such copies;

25 That the reading and signing of
the deposition was not waived;

That I am not related to any of
the parties hereto, nor interested in the
outcome of the action and have no contract
with any parties, attorneys or persons with
an interest in the action that has a
substantial tendency to affect my
impartiality;

WITNESS MY HAND AND SEAL this 10th
day of July, 2015.

22
23

24 _____
Alexis Jensen
Notary Public

25

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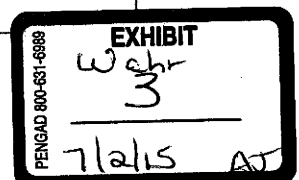
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APPLICANT INFORMATION	
*OWNER OF MARK	Innovative Pulmonary Solutions, Inc.
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To the Commissioner for Trademarks:

MARK: HOLAIRA (Standard Characters, see mark)

The literal element of the mark consists of HOLAIRA.

The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, Innovative Pulmonary Solutions, Inc., a corporation of Delaware, having an address of
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United States

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

International Class 010: Medical devices; medical apparatus and instruments

Intent to Use: The applicant has a bona fide intention to use or use through the applicant's related company or licensee the mark in commerce on or in connection with the identified goods and/or services. (15 U.S.C. Section 1051(b)).

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A fee payment in the amount of \$325 has been submitted with the application, representing payment for 1 class(es).

Declaration

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

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HOLAIRA

Word Mark

HOLAIRA

Translations

The wording "HOLAIRA" has no meaning in a foreign language.

Goods and Services

IC 010. US 026 039 044. G & S: Medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases

Standard Characters Claimed

Mark Drawing Code

(4) STANDARD CHARACTER MARK

Serial Number

85806379

Filing Date

December 19, 2012

Current Basis

1B

Original Filing Basis

1B

Published for Opposition

December 3, 2013

International Registration Number

1167434

Owner

(APPLICANT) HOLAIRA, INC. CORPORATION DELAWARE SUITE 105 3750 ANNAPOLIS LANE PLYMOUTH MINNESOTA 55447

Assignment Recorded

ASSIGNMENT RECORDED

Attorney of Record

Barbara J. Grahn

Type of Mark

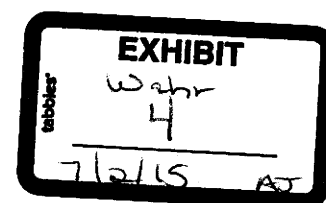
TRADEMARK

Register

PRINCIPAL

Live/Dead Indicator

LIVE

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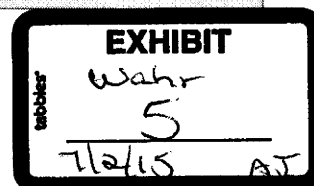
Trademark/Service Mark Application, Principal Register

Serial Number: 85914385

Filing Date: 04/25/2013

The table below presents the data as entered.

Input Field	Entered
SERIAL NUMBER	85914385
MARK INFORMATION	
*MARK	<u>DNERVA</u>
STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	DNERVA
MARK STATEMENT	The mark consists of standard characters, without claim to any particular font, style, size, or color.
REGISTER	Principal
APPLICANT INFORMATION	
*OWNER OF MARK	Holaira, Inc.
INTERNAL ADDRESS	Suite 105
*STREET	3750 Annapolis Lane
*CITY	Plymouth
*STATE (Required for U.S. applicants)	Minnesota
*COUNTRY	United States
*ZIP/POSTAL CODE (Required for U.S. applicants only)	55447
LEGAL ENTITY INFORMATION	
TYPE	corporation
STATE/COUNTRY OF INCORPORATION	Delaware
GOODS AND/OR SERVICES AND BASIS INFORMATION	
INTERNATIONAL CLASS	010



*IDENTIFICATION	Medical devices; medical apparatus and instruments
FILING BASIS	SECTION 1(b)
ATTORNEY INFORMATION	
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ATTORNEY DOCKET NUMBER	24450-2004
FIRM NAME	Oppenheimer Wolff & Donnelly, LLP
INTERNAL ADDRESS	Suite 2000
STREET	222 South Ninth Street
CITY	Minneapolis
STATE	Minnesota
COUNTRY	United States
ZIP/POSTAL CODE	55402
PHONE	612-607-7325
FAX	612-607-7100
EMAIL ADDRESS	bgrahn@oppenheimer.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
OTHER APPOINTED ATTORNEY	Erika Koster, Barbara Wrigley, Ed Laine, Sam Hellfeld, Andrew Hansen, Dennis Hansen, Aaron Scott
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INTERNAL ADDRESS	Suite 2000
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STATE	Minnesota
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ZIP/POSTAL CODE	55402
PHONE	612-607-7325
FAX	612-607-7100
EMAIL ADDRESS	bgrahn@oppenheimer.com;ipdocket@oppenheimer.com

AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
FEE INFORMATION	
NUMBER OF CLASSES	1
FEE PER CLASS	325
*TOTAL FEE DUE	325
*TOTAL FEE PAID	325
SIGNATURE INFORMATION	
SIGNATURE	/dennis wahr/
SIGNATORY'S NAME	Dennis W. Wahr
SIGNATORY'S POSITION	CEO
DATE SIGNED	04/25/2013

Trademark/Service Mark Application, Principal Register

Serial Number: 85914385

Filing Date: 04/25/2013

To the Commissioner for Trademarks:

MARK: DNERVA (Standard Characters, see mark)

The literal element of the mark consists of DNERVA.

The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, Holaira, Inc., a corporation of Delaware, having an address of
Suite 105,
3750 Annapolis Lane
Plymouth, Minnesota 55447
United States

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

International Class 010: Medical devices; medical apparatus and instruments

Intent to Use: The applicant has a bona fide intention to use or use through the applicant's related company or licensee the mark in commerce on or in connection with the identified goods and/or services. (15 U.S.C. Section 1051(b)).

The applicant's current Attorney Information:

Barbara J. Grahm and Erika Koster, Barbara Wrigley, Ed Laine, Sam Hellfeld, Andrew Hansen, Dennis Hansen, Aaron Scott of Oppenheimer Wolff & Donnelly, LLP

Suite 2000
222 South Ninth Street
Minneapolis, Minnesota 55402
United States

The attorney docket/reference number is 24450-2004.

The applicant's current Correspondence Information:

Barbara J. Grahm
Oppenheimer Wolff & Donnelly, LLP
Suite 2000
222 South Ninth Street
Minneapolis, Minnesota 55402
612-607-7325(phone)

612-607-7100(fax)

bgrahn@oppenheimer.com;ipdocket@oppenheimer.com (authorized)

A fee payment in the amount of \$325 has been submitted with the application, representing payment for 1 class(es).

Declaration

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Declaration Signature

Signature: /dennis wahr/ Date: 04/25/2013

Signatory's Name: Dennis W. Wahr

Signatory's Position: CEO

RAM Sale Number: 85914385

RAM Accounting Date: 04/25/2013

Serial Number: 85914385

Internet Transmission Date: Thu Apr 25 11:39:10 EDT 2013

TEAS Stamp: USPTO/BAS-70.102.26.226-2013042511391098

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4-DA-9156-20130424194812306502

DNERVA



United States Patent and Trademark Office

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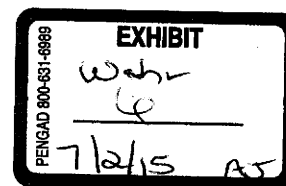
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DNERVA



Word Mark	DNERVA
Goods and Services	IC 010. US 026 039 044. G & S: Medical devices for treating obstructive lung diseases; medical apparatus and instruments for treating obstructive lung diseases
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85914385
Filing Date	April 25, 2013
Current Basis	1B
Original Filing Basis	1B
Published for Opposition	April 15, 2014
International Registration Number	1181913
Owner	(APPLICANT) Holaira, Inc. CORPORATION DELAWARE Suite 105 3750 Annapolis Lane Plymouth MINNESOTA 55447
Attorney of Record	Barbara J. Grahm
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

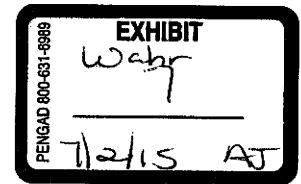
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COPD - definition of COPD by Medical dictionary

<http://medical-dictionary.thefreedictionary.com/COPD>

COPD

Also found in: **Dictionary/thesaurus, Legal, Acronyms, Encyclopedia, Wikipedia.**



chronic [kron'ik]

persisting for a long time; applied to a morbid state, designating one showing little change or extremely slow progression over a long period.

chronic airflow limitation (CAL) any pulmonary disorder occurring as a result of increased airway resistance or of decreased elastic recoil; the diseases most often associated are **ASTHMA**, chronic **BRONCHITIS**, and chronic pulmonary **EMPHYSEMA**. Called also **chronic obstructive pulmonary disease**.

Chronic airflow limitation has the highest morbidity rate of any significant chronic pulmonary disorder in the United States and is the second most common cause of hospital admissions. It is difficult to estimate its exact incidence because most diseases of the respiratory tract are not reportable and there is some confusion in definition of terms related to diseases of this type. However, the Social Security Administration reports that CAL ranked only second to heart disease as the cause of disability in men over the age of 40. The incidence of CAL is increasing and, although not all specific causes are known, factors contributing to its development and affecting its degree of severity have been identified. Heavy cigarette smoking is probably the most important factor, and others are industrial pollution, occupational exposure to irritating inhalants, allergy, autoimmunity, genetic predisposition, and chronic infections.

Prevention is best accomplished through education of the public about the hazards of cigarette smoking and air pollution and the need for early detection and prompt treatment of respiratory disorders that could become chronic in nature. The American Lung Association is particularly interested in education of lay persons in these matters and in the prevention of all types of respiratory disorders. This agency, which has local offices distributed throughout the country, is an excellent source of information about prevention and the latest developments in the treatment of respiratory diseases.

SYMPTOMS. This is an insidious disease that can develop into advanced lung damage almost before its victim is aware that the condition is serious. The early symptoms are shortness of breath upon exertion, a mild cough (sometimes called "smoker's cough"), which occurs most often in the morning, and easy fatigability that follows even minimal physical effort. Prompt treatment of these symptoms can forestall the more serious effects of extensive lung damage; however, the destruction of lung tissue and bronchial mucosa damage that has already occurred by the time these symptoms appear is irreversible.

As the disease progresses, the symptoms of dyspnea, weakness, and cough become more severe. The patient has difficulty expelling air from the lungs and the cough becomes more productive of thick, tenacious sputum. The patient looks anxious and drawn and may speak in short, hesitant sentences. Symptoms related to disturbances of the respiratory and circulatory systems and **ACID-BASE BALANCE** may appear as these complications develop.

COMPLICATIONS. Destructive involvement of respiratory structures and the resultant impairment of circulatory function can produce serious life-threatening complications. Among these are acute respiratory failure, disturbance in the acid-base balance (which can occur either as uncompensated **respiratory ACIDOSIS** or metabolic **ALKALOSIS**), bronchopulmonary infections, **COR PULMONALE** (the result of increased resistance in

pulmonary circulation), **pulmonary EMBOLISM** (especially if polycythemia is severe), and **PEPTIC ULCER**. **BLOOD GAS ANALYSIS** is helpful in evaluating effectiveness of blood gas exchange across alveolar walls. In severe chronic airflow limitation, the PaCO_2 level is high while the PaO_2 and the SaO_2 levels are low.

TREATMENT AND PATIENT CARE. In general, treatment is concerned with restoring and maintaining existing lung function, relieving symptoms, and planning a program of rehabilitation tailored to accommodate the individual patient's physiologic needs, physical stamina, vocational needs, lifestyle, and personality. Specific measures of patient care are concerned with (1) initial and periodic evaluation of patient status, (2) maintenance of general health as much as possible, (3) prevention and control of infection, (4) improvement of ventilation, and (5) patient education.

Chronic airflow limitation is a disease that has no cure; its chronic nature requires an ongoing program of assessment and long-term care that is planned and revised as the patient's needs dictate. Whatever the patient care setting—acute care facility, out-patient clinic, long-term care facility, or home—the elements of care presented below are essential to the effective management of the condition.

Evaluation. Patient assessment begins with the taking of the patient's history and performing physical examination and lung function tests at the time the diagnosis is established. These measures, along with blood gas analysis at rest and after exercise, provide a baseline for periodic evaluation of the patient's status to determine the progress of the disease and the effectiveness of treatment.

When patients are informed about the purpose of the tests and therapy they are more likely to participate in the planned regimen of care and to become motivated to continue carrying out their responsibilities in the management of their illness. Those who work with the patient should clarify the goals and offer encouragement when they make progress toward those goals, no matter how slight the improvement might be. This implies, of course, that all members of the health care team have an understanding of the disease, the meaning of various test values, and the purpose of each aspect of care.

Maintenance of Health Status. It is important to communicate to these patients the concept of health status, particularly in regard to their position on the health-illness continuum. They cannot be completely disease-free or restored to their former state of health. They can, however, manage the disease symptoms for periods of time and some may even make progress toward a better state of health. For those patients who continue to deteriorate despite appropriate care, encouragement should be provided to maintain as much function as possible.

Poor appetite and the potential for dehydration are problems commonly associated with pulmonary disease. Purulent sputum, coughing, and fatigue can contribute to loss of interest in eating. Mouth breathing, increased respiratory rate, and frequent expectorating contribute to the loss of fluid.

Frequent oral hygiene and mouth care can help diminish mouth odor and unpleasant taste. A short period of rest just prior to each meal can help overcome the problem of fatigue. Meals should be spaced so that the stomach is not overloaded at any one time; five small meals, rather than three a day, can help avoid overfilling of the stomach and interference with breathing. Postural drainage and similar procedures should not be done on a full stomach, nor should they be scheduled just before a meal. Adequate hydration can be accomplished by an intake of at least 3000 ml of liquid each day. Unless contraindicated, this should include bouillon, fruit juices, and other liquids the patient finds enjoyable and refreshing.

Physical activity may be severely limited by CAL because of inadequate ventilation and decreased circulation. As with all other aspects of patient care, plans to increase exercise tolerance and promote physical activity should be designed according to the patient's cardiopulmonary status. Techniques to promote muscular relaxation and breathing control are the first step, followed by gradual increase in activity as the patient's progress and general physical condition permit.

Adequate rest is essential, but the **HAZARDS OF IMMOBILITY** must be avoided, especially in patients who are fearful that any physical activity may precipitate an exhausting episode of coughing and dyspnea. The goal is to provide sufficient rest so that the body's natural restorative processes can work, but to avoid long periods of sleeping and lying in bed during the day.

When the patient's cardiopulmonary condition is such that bed rest is prescribed, care is taken to avoid complete physical inactivity, which will only serve to increase problems of inadequate ventilation and muscle weakness. Proper positioning is essential and should be such that the neck is extended, with the chin well off the chest. Support under the thighs while the patient is supine will release tension on abdominal muscles, thereby facilitating movement of the diaphragm for deep breathing and effective coughing. The arms and hands should also be supported on pillows and positioned away from the sides to allow for maximum lung expansion without elevation of the upper chest. A foot board is placed so as to maintain good posture, promote comfort, and ensure good muscle tone in the legs and feet.

Prevention and Control of Infection. Acute respiratory infection can be fatal in patients with chronic airflow limitation. Chronic infections inflict further damage to the respiratory structures, lead to increased debilitation, and increase the likelihood of severe complications. Both acute and chronic infections produce increased secretions in the air passages, which further restrict the flow of air.

Contact with others who have an upper respiratory infection should be avoided, as should being in large crowds during the season when such infections are common. A high level of resistance should be maintained through good personal hygiene and adequate nutrition. Vaccines to guard against influenza are recommended. Patients should be taught to watch for changes in color and amount of sputum. If a change in sputum or any other symptoms of infection appear, this should be reported.

Improvement of Ventilation. It is obvious that measures to improve ventilation in the patient with CAL are of primary importance, and perhaps that is why so many ways have been devised to facilitate the flow of air to and from the lungs. Breathing is most difficult during the expiratory phase, making it difficult to remove trapped air and secretions. In addition, the bronchial walls are weakened in patients with emphysema and are subject to collapse. Health status and physical condition at the time the technique is used will affect the choice of method and its effectiveness.

Hydration is considered especially valuable in improvement of ventilation. Inhaled air should be moist so as to thin the secretions for removal and soothe the irritated mucous membranes. This can be accomplished through the use of vaporizers and humidifiers, either for environmental humidification in the patient's room or in conjunction with oxygen therapy and the administration of aerosols. Oral intake of fluids is also important. Bronchodilators, usually in the form of aerosols, sometimes as oral medications, are usually prescribed. The aerosol method of delivery depends on the ability of the patient to breathe deeply so that the medication reaches the lower segments of the respiratory tract.

Controlled deep breathing patterns are especially helpful in emptying the lungs and providing adequate ventilation. The patient with CAL is taught to expand the lower chest and to use the accessory muscles

and diaphragm to improve the breathing pattern. Performance of these breathing patterns is important because patients probably are not in the habit of breathing in the most effective manner, making optimum use of remaining pulmonary function. The patient is taught slow, controlled, and steady breathing. Respiratory effort should be concentrated on slow expiratory flow through parted or pursed lips. Pushing the air out of the lungs too forcefully can bring on collapse of the airway structures. During instruction, the caregiver watches for signs of exhaustion and warns against overdoing the deep breathing until the patient has adjusted to it. A correct breathing pattern should be coordinated with all of the patient's daily activities so that it becomes habitual and is done without too much thought.

Effective coughing does not come easily to patients with this condition. They may have experienced too many episodes in which a dry hacking cough has caused exhaustion, increased dyspnea, and prevented removal of tenacious sputum from the air passages. They must be convinced that, when done correctly, coughing can remove mucous plugs and relieve rather than produce dyspnea. Patients should be warned that explosive coughing is not very effective, can damage the airways, and can lead to exhaustion. The objective of coughing is to move secretions upward gradually so that they can be expectorated.

POSTURAL DRAINAGE is also valuable in facilitating the removal of mucus from the air passages. The various maneuvers involved in this procedure are designed to take advantage of gravity flow as a means of clearing specified segments of the air passages when normal air flow is not sufficient to move secretions or stimulate the cough reflex. Chest percussion and vibration may be employed during postural drainage to loosen secretions. **OXYGEN THERAPY** is used as a supportive measure when there is decreased oxygenation of arterial blood. It can be administered to ambulatory patients being cared for at home. Blood gas analysis is an excellent guide in determining the need for initiating oxygen therapy and for monitoring dosage.

Patient Education. As with all chronic diseases that require long-term planning and management, patient education is of primary importance in successful execution of the plan. Each of the measures previously described involves instruction of the patient and family, particularly when care is carried out on an outpatient basis. The patient should be told *why* it is necessary to stop smoking, avoid other irritating inhalants, carry out good health practices, take medication only as prescribed, and faithfully perform techniques to improve ventilation. Those patients who follow the exercises prescribed for them often find they can lead more active lives than formerly. Exertional dyspnea becomes less severe and complications from infections caused by bacteria in secretions formerly trapped in the respiratory tract are less frequent. Active participation in a program of self-care gives these patients a sense of control and improves their self-esteem.

chronic fatigue syndrome (chronic fatigue and immunodeficiency syndrome) persistent debilitating fatigue of recent onset, with reduction of physical activity to less than half of usual, accompanied by some combination of muscle weakness, sore throat, mild fever, tender lymph nodes, headaches, and depression, with the symptoms not attributable to any other known causes. Its nature is controversial; viral infection (including Epstein-Barr virus and human herpesvirus-6) may be associated with it, but no causal relationship has been demonstrated. A number of names have been used for this syndrome, including Iceland disease and benign myalgic encephalomyelitis.

chronic granulomatous disease chronic suppurative lymphadenitis, eczematoid dermatitis, enlargement of the liver and spleen, and chronic pulmonary disease associated with a genetically determined defect in the intracellular bactericidal function of leukocytes.

chronic obstructive lung disease (COLD) (chronic obstructive pulmonary disease (COPD)) chronic airflow limitation.

chronic regional pain syndrome reflex sympathetic dystrophy.

Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition. © 2003 by Saunders, an imprint of Elsevier, Inc. All rights reserved.

COPD

Abbreviation for **chronic obstructive pulmonary disease.**

Farlex Partner Medical Dictionary © Farlex 2012

COPD chronic obstructive pulmonary disease.

Dorland's Medical Dictionary for Health Consumers. © 2007 by Saunders, an imprint of Elsevier, Inc. All rights reserved.

COPD

abbr.

chronic obstructive pulmonary disease

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COPD,

abbreviation for **chronic obstructive pulmonary disease.**

Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier.

COPD Chronic obstructive pulmonary disease Pulmonology An umbrella term for a group of usually progressive lung disorders with overlapping signs and symptoms, including asthma, bronchiectasis, chronic bronchitis, and emphysema; COPD, usually associated with a long Hx of cigarette smoking, is the 5th most common COD—65,000 deaths/yr, US, the 3rd most common—after heart diseases and schizophrenia—cause of chronic disability of older individuals, and the most common cause of pulmonary HTN and cor pulmonale in the US; the major COPD lesions, chronic bronchitis and emphysema, commonly coexist; the former is responsible for the alveolar hypoxia, ↓ PO₂, ↑ CO₂, and ↓ pH that lead to pulmonary HTN, which is seen in 65% of ♂ at autopsy and 15% of ♀, and is due to the unopposed effect of elastases in the lungs Clinical SOB, wheezing, chronic cough Diagnosis Clinical Hx, PE, pulmonary function tests Complications Bronchitis, pneumonia, lung cancer; Pts with COPD have been divided into type A with emphysema, fancifully known as 'pink puffers' and type B with chronic bronchitis—'blue bloaters'; respiratory function and dyspnea in severe COPD may improve with theophylline, which improves respiratory-muscle function Management Bronchodilators, O₂ for advanced disease Prevention Smoking cessation, ↑ dietary n-3 polyunsaturated fatty acids may protect against COPD, possibly by interfering with the

production of inflammatory mediators, including leukotrienes, platelet-activating factor, IL-1 and TNF. See **Emphysema**.

Management of COPD

Minimize airflow restriction

Reduce production of secretions

↑ Eliminate secretion

Bronchodilatation

Sympathomimetic agents, eg inhaled β_2 -adrenoreceptor agonists

Anticholinergic agents, eg ipratropium, nebulized atropine

Theophylline

Corticosteroids—maximum benefit in 1st 2 wks of therapy (NEJM 1999; 340:1941oa)

Correct 2° physiologic alterations

Hypoxemia—O₂ administration

Pulmonary hypertension and cor pulmonale

Hypercapnia

Optimize functional capacity

Exercise conditioning

Upper extremity training

Respiratory muscle training

Respiratory muscle rest

Dyspnea

Nutrition

Physical and occupational therapy

Psychosocial rehabilitation

Other issues of management

α_1 -antitrypsin augmentation

Bullectomy

Lung transplantation

Antibiotics with exacerbations

Smoking cessation

McGraw-Hill Concise Dictionary of Modern Medicine. © 2002 by The McGraw-Hill Companies, Inc.

COPD

Abbreviation for chronic obstructive pulmonary disease.

Medical Dictionary for the Health Professions and Nursing © Farlex 2012

Chronic obstructive pulmonary disease (COPD)

A term used to describe chronic lung diseases, like chronic bronchitis, emphysema, and asthma.

Mentioned in: **Bronchitis**

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chronic obstructive airway disease; COAD; chronic obstructive pulmonary disease; COPD; chronic obstructive lung disease; COLD airway dysfunction (e.g. chronic bronchitis or emphysema) in cigarette smokers, or ex-smokers; presenting as type A, 'pink puffers' (breathlessness but near normal arterial oxygen and carbon dioxide levels), or type B, 'blue bloaters' (no breathlessness, but marked arterial hypoxia, carbon dioxide retention and polycythaemia)

Illustrated Dictionary of Podiatry and Foot Science by Jean Mooney © 2009 Elsevier Limited. All rights reserved.

COPD

Abbreviation for chronic obstructive pulmonary disease.

Medical Dictionary for the Dental Professions © Farlex 2012

COPD

chronic obstructive pulmonary disease (COPD).

Saunders Comprehensive Veterinary Dictionary, 3 ed. © 2007 Elsevier, Inc. All rights reserved

Patient discussion about COPD

Q. Yoga for COPD? I was diagnosed with COPD two years ago, and so far I manage to keep on with my life, although I stopped my regular exercise. A friend of mine that also has COPD told me about yoga exercises for COPD patients- Does anyone here knows something about it?

A. Yoga can teach you how to breath properly, and is also a very good exercise. It's also very relaxing which is also good for you lung, and you can enjoy it. Just give it a try, but ask your physician first.

Q. (COPD)chronic obstructive pulmonary disease the main causes of?

A. Mainly smoking, although ambient air pollution and industrial exposure to dust have also been implicated as causes.

You may read more here:

www.mayoclinic.com/health/copd/DS00916

More discussions about COPD

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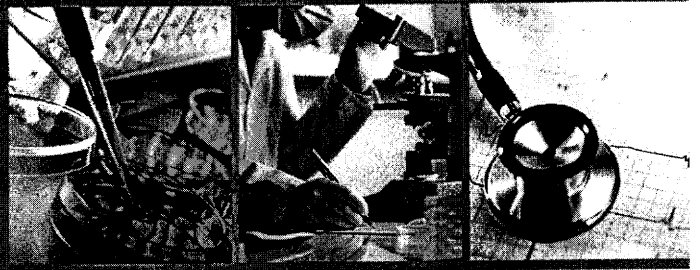
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A Mode Tend Parenting Partnership

The 25th Annual Piper Jaffray Healthcare Conference

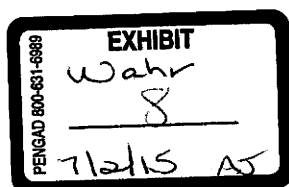
DECEMBER 3-4, 2013 IN NEW YORK CITY



Holaira

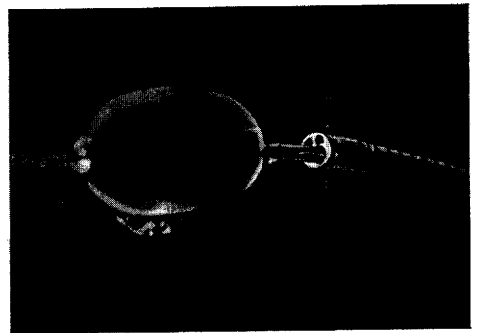
GUIDES FOR
THE JOURNEY. | PiperJaffray.

Holaira000001



Holaira: Treatment for COPD & Asthma

- Addresses unmet clinical need
- Easy to use
- Reduce health care costs
- Massive markets

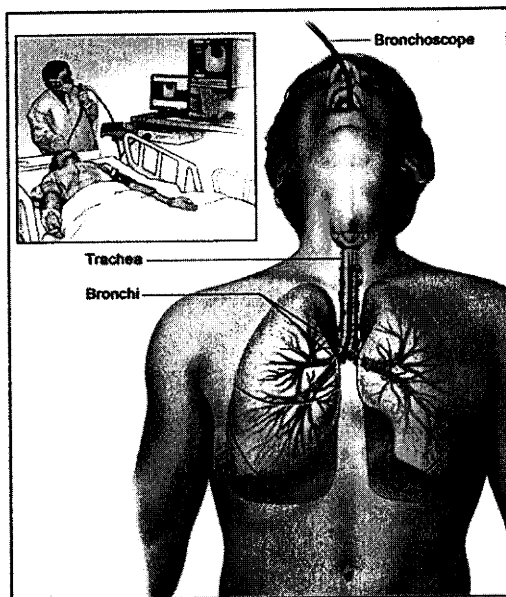


Current Status

- Novel Concept: Exceptional IP position
- Exciting human data with 12 month follow up
- Proven leadership team

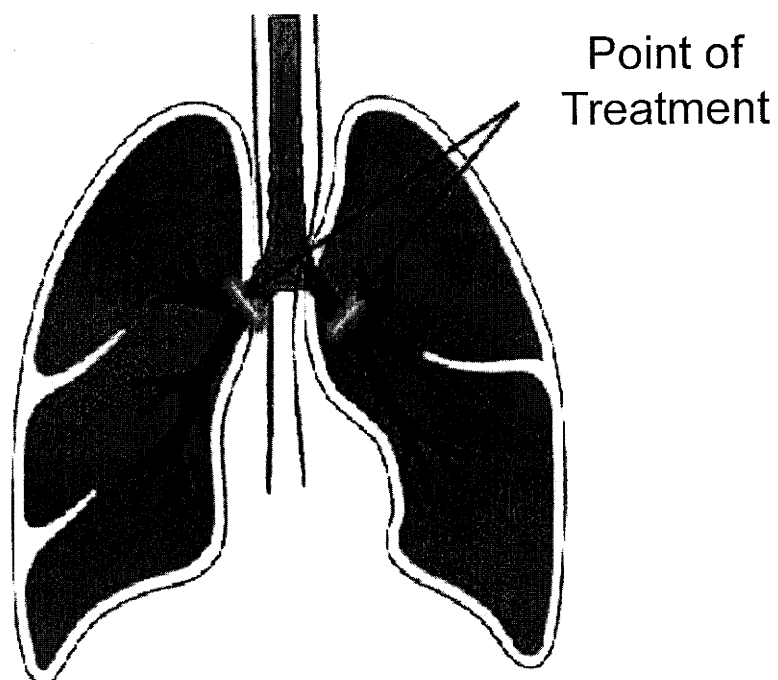
Positioned to achieve meaningful value builders

Targeted Lung Denervation (TLD)

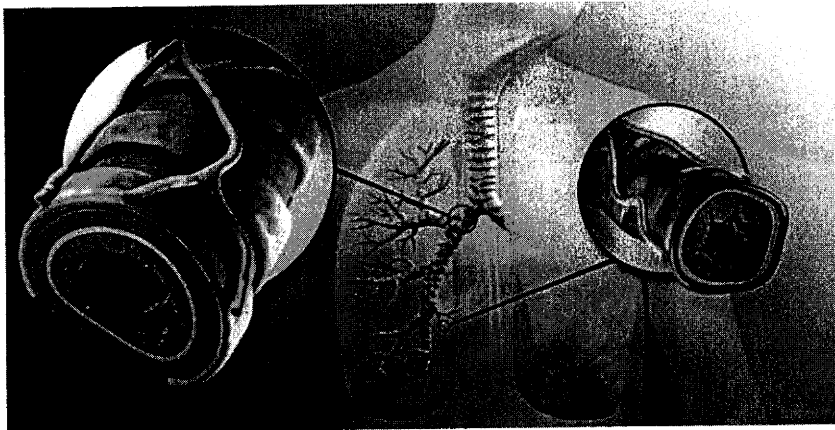


- Employs RF energy to ablate the nerve input to the lungs which will:
 - Induce a generalized bronchodilation
 - Decrease mucus production
 - Decrease inflammation
- Outpatient procedure with sustained benefit

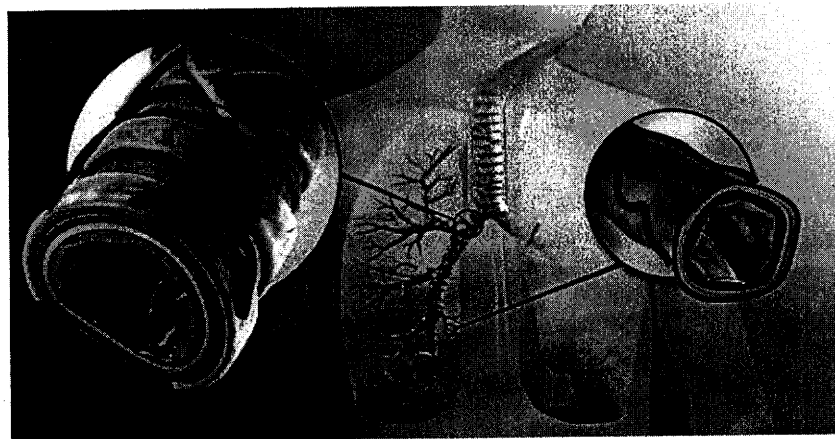
Targeted Lung Denervation (TLD)



Before / After TLD Therapy



Before



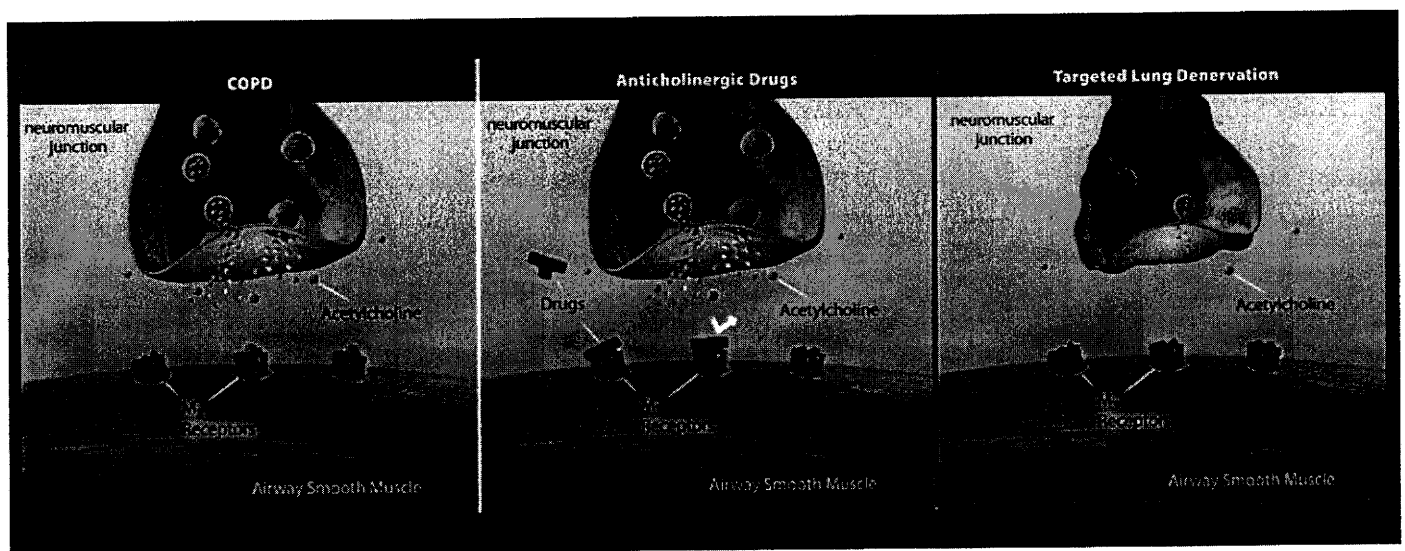
After

4


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TLD Mechanism of Action well understood



Targeted Lung Denervation reduces acetylcholine release from the nerve ending resulting in:

- Smooth muscle cell relaxation
- Sustained airway dilation

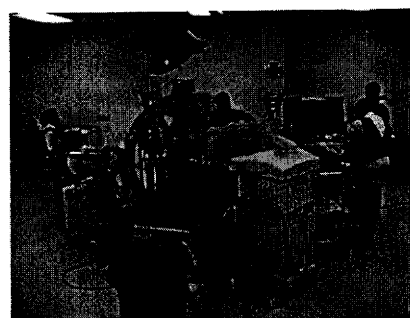
Clinical benefits: TLD vs Drugs

	TLD	Anticholinergic Medications
Lung Distribution	Whole lung	Incomplete
Adherence	Sustained benefit	Poor
Misuse	Sustained benefit	Poor
Peak/trough variation	Stable benefit	Unavoidable
Potential synergistic effect	Yes	

- Not subject to limitations of medication but with potential for synergistic effect

Preclinical Animal Studies

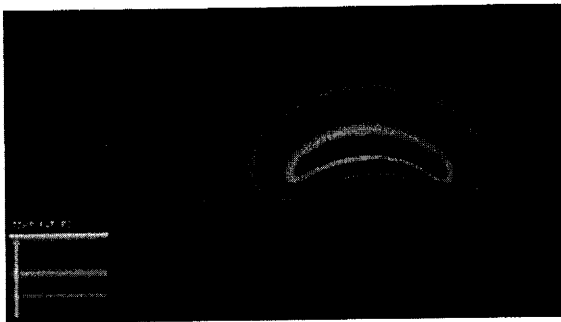
Animal Studies Summary	
• Studies performed	14
• Animals studied	94
• Airways treated	187
• Activations delivered	1099
• Days of longest follow-up	640
• Days in life	10,221



Major Findings:

- TLD disrupts bronchial nerve branches and improves airway resistance
- Effect of TLD sustained for almost 2 years
- Depth of effect tunable based on power
- Surface cooling with balloon protects airway surface and prevents stenosis

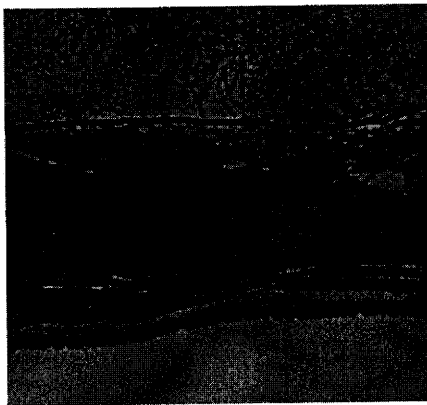
Surface Protection is key



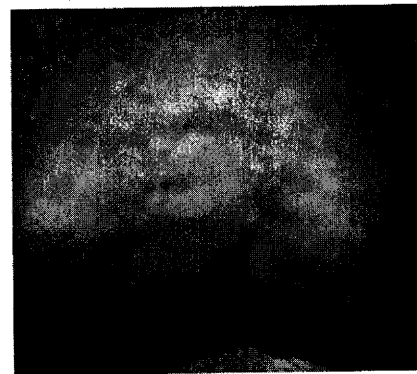
> 120 Bench-top thermal tests

Surface protection and dosing —
seen and quantified

- Bench top
- Ex vivo
- In vivo



8 > 1300 In vivo animal histology



560 Ex vivo ablations

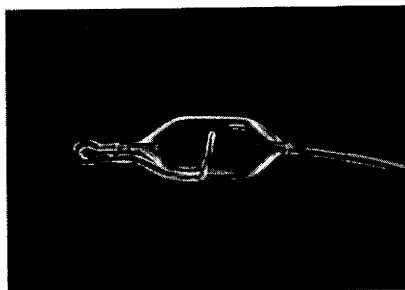
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Holaira™ Lung Denervation System

Catheter Features

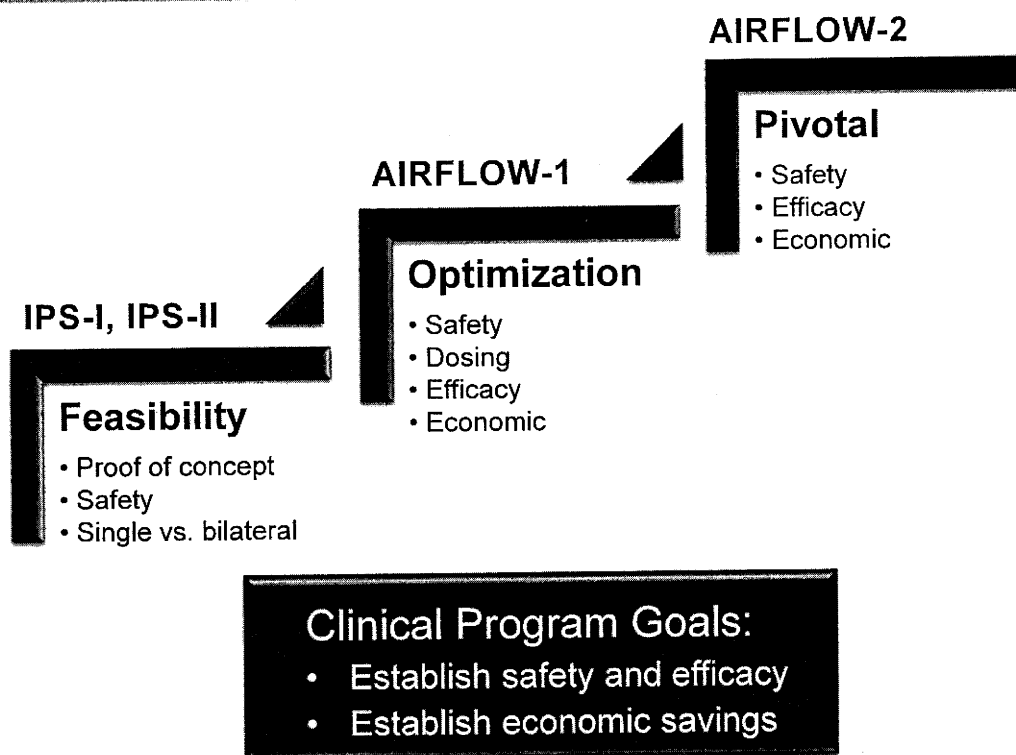


- Electrode requires only 4 activations
- Balloon:
 - Dual cooled
 - Compliant: “one size fits all”

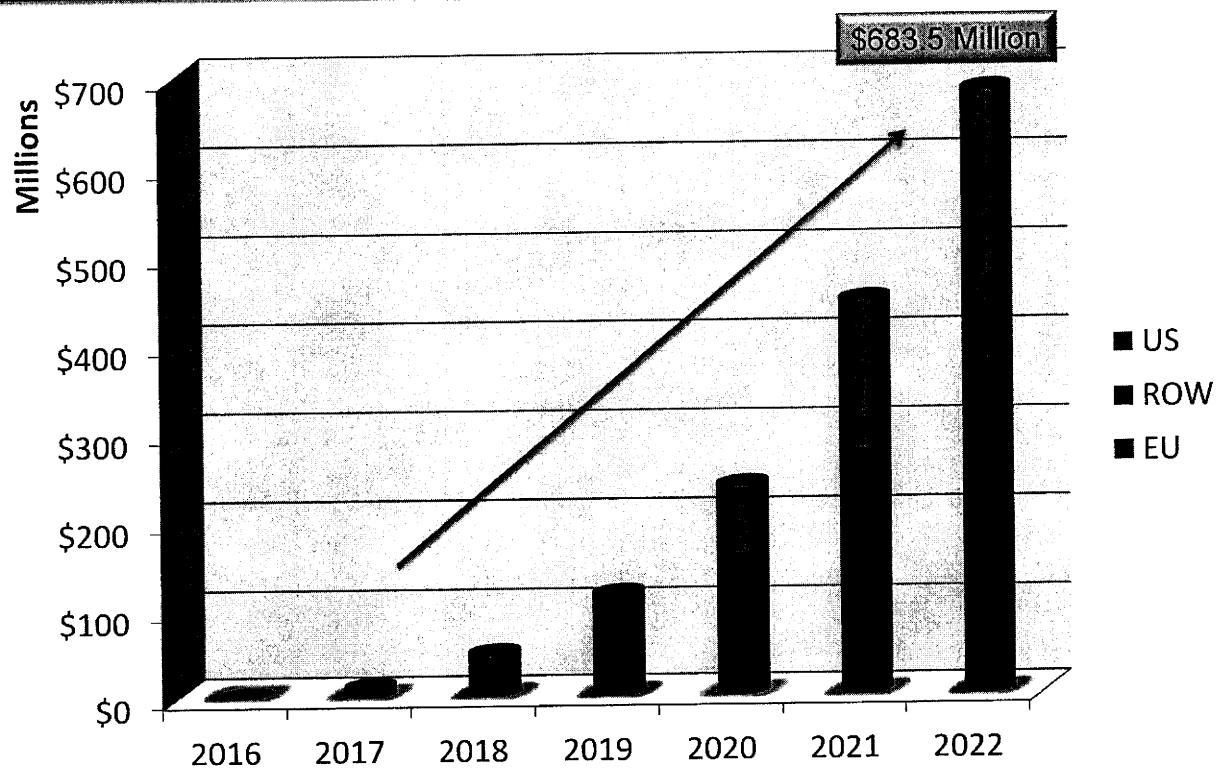
- Visualization for optimal placement



COPD Clinical Program Overview



WW Revenue Projections



- 166,000 TLD Catheters in 2022
- COPD and Asthma indication split 70/30 in 2022

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Obstructive Airway Disease: Competitive Landscape

Company/Product	COPD Large Population	Asthma Intermediate Population	Emphysema Smaller Population	MOA	Ease of Use
Boehringer Ingelheim/ Spiriva	✓	✓	✓	<u>Temporary block of acetylcholine receptors</u>	Inhaler
Holaira	✓	✓	✓	<u>Targeted Lung Denervation</u> <ul style="list-style-type: none"> • Sustained block of acetylcholine release • Ease of use advantage 	
BSC (formerly Asthmatx)/ Alair®		✓		<u>Smooth muscle cell ablation</u>	Requires 3 outpatient procedures, > 200 total ablations in small airways
PneumRx/RePneu™ Pulmonx/Zephyr® Olympus/ IBV Valve System Aeris Therapeutics/AeriSeal Uptake Medical/Intervapor™			✓	<u>Lung Volume Reduction</u>	Challenging planning required

90+ portfolio of patents, applications and licenses

- Owned by Holaira
 - 5 US patents
 - 3 foreign patents (Europe, China, Japan)
 - 23 pending US
 - 1 pending PCT
 - 9 pending EU
 - 6 pending Japan, China
 - 9 other foreign
- Under Non-Exclusive License
 - 11 US applications pending
 - 12 US Patents
 - 2 PCT applications pending
 - 2 foreign applications pending
 - 2 foreign Patents (Europe, Australia)
- Under Exclusive License
 - 4 US Patents
 - 1 US application pending
 - 1 PCT application pending

Investment exceeds \$1.5M in external expenses
Filings in 80% of global market

Current Investors & Board Members

Investors

Versant Ventures

Morgenthaler Ventures

Split Rock Ventures

Advanced Technology Ventures

Board Members

Dennis Wahr M.D., President and CEO

Mike Carusi, Advanced Technology Ventures

Mark Deem, The Foundry

Kirk Nielsen, Versant Ventures

Hank Plain, Morgenthaler Ventures

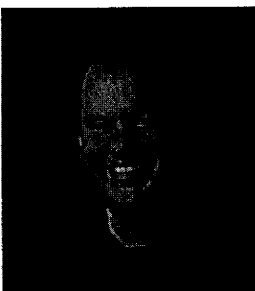
Dave Stassen, Split Rock Ventures

Management Team



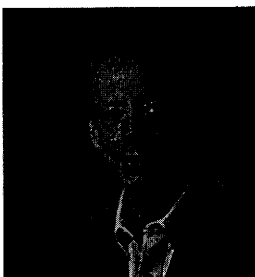
Dennis Wahr, M.D: President & CEO

- Founder, Pres. and CEO both Lutonix & Velocimed
- Board certified Interventional Cardiologist



Martin Mayse, M.D: Founder and CTO

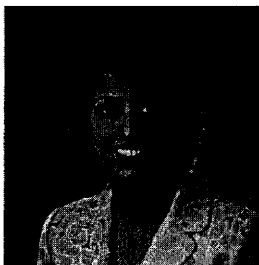
- Former Director Interventional Pulmonology at Wash Univ
- Board certified Pulmonologist
- Biomedical Engineer



Steve Mertens: Senior VP Operations

- Sr. VP R&D Boston Scientific
- >20yrs biomedical engineer experience
- MBA

Management Team



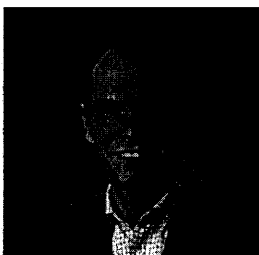
Mahtab Fatemi, JD: Director of Regulatory Affairs

- Director Regulatory Affairs at MAP Pharmaceuticals
- >14 yrs regulatory science experience (US RAC)
- Masters Degree Science, JD Degree, State Bar of California



Kari Kubesh: CFO

- VP Finance at Lutonix
- CPA, >17yrs finance experience, public and private companies
- >10 years venture capital backed medical device companies



Jim Pavliska: VP Clinical

- Clinical Director Lutonix and Velocimed
- >15 yrs clinical research experience
- Managed > 12 US and International Clinical trials

Series D Financing Highlights

- Amount
 - \$40 million
 - Finances company through December 2016
 - Full Insider participation
- Milestones Through 2016
 - Clinical
 - COPD:
 - 12 month data from Phase II randomized study
 - 3 yr data from feasibility studies
 - IDE for US Pivotal Trial
 - Asthma
 - 6 month data from asthma feasibility study
 - Dominant position in new field of pulmonary denervation
 - Exceptional IP portfolio
 - Multiple year first mover access to US markets
 - OUS Revenue



THANK YOU

HOLAIRA

Breathe easier. For life.™

Holaira000019

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD**

In the matter of Application Serial No.: 85/806,379

Filed: December 19, 2012

For the mark: HOLAIRA

Published in the *Trademark Official Gazette* on December 3, 2013

Boston Scientific Corporation and
Asthmatx, Inc.

Opposition No. 91215699

Opposers,

v.

**AFFIDAVIT OF SERVICE
BY UNITED STATES MAIL**

Holaira, Inc.

Applicant.

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)


Debra Peterfeso, being first duly sworn upon oath, states that on July 28, 2015, she served the attached:

1. CD with the deposition transcript of Dr. Dennis Wahr, Exhibits 1-9, and 11; and
2. Errata sheet of Dr. Dennis Wahr,

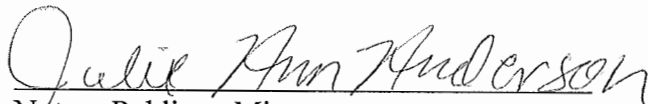
upon the within named counsel by United States Mail, using an envelope addressed as set forth below, with postage prepaid, and depositing the same in the United States Mail at Minneapolis, Minnesota:

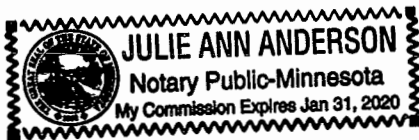
Timothy D. Sitzmann, Esq.
Stephen R. Baird, Esq
Bradley J. Walz, Esq.
Winthrop & Weinstine
Capella Tower, Suite 3500
225 South Sixth Street
Minneapolis, MN 55402-4629

Attorneys for Opposers


DEBRA PETERFESO

Subscribed and sworn to before
this 28th day of July, 2015


Notary Public – Minnesota
My Commission Expires Jan. 31, 2020



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
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STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

Debra Peterfeso, being first duly sworn upon oath, states that on November 16, 2015, she served the attached:

1. CD with deposition transcripts of Dr. Dennis Wahr (redacted and unredacted versions), Exhibits 1-9, and 11; and
2. Signed errata sheet of Dr. Dennis Wahr,

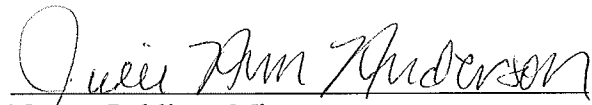
upon the within named counsel by United States Mail, using an envelope addressed as set forth below, with postage prepaid, and depositing the same in the United States Mail at Minneapolis, Minnesota:

Timothy D. Sitzmann, Esq.
Stephen R. Baird, Esq
Bradley J. Walz, Esq.
Winthrop & Weinstine
Capella Tower, Suite 3500
225 South Sixth Street
Minneapolis, MN 55402-4629

Attorneys for Opposers


DEBRA PETERFESO

Subscribed and sworn to before
this 16th day of November, 2015



Notary Public – Minnesota
My Commission Expires Jan. 31, 2020

